2023

Celebrating 25 Years

Indian Analytical Instruments Association

IAIA

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MARKET DYNAMICS OF ANALYTICAL & LIFE SCIENCE INSTRUMENTATION IN INDIA

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2023

Celebrating 25 Years

IAIA

Market Dynamics of Analytical and Life Science Instrumentation in India

IAIA – Indian Analytical Instruments Association
No.205, Solaris I, Saki Vihar Road
Powai, Mumbai – 400 072
+91 9967061333 www.iaia.org.in email: info@iaia.org.in

Chandrahas Shetty
President
Indian Analytical Instruments Association

Its indeed a pleasure and honor to be the President of Indian Analytical Instruments Association, which has renowned Analytical Instruments manufacturers from all over the world including Indian manufacturers and also companies who are distributors, resellers etc., for Analytical Instruments manufacturers as its members. Together we are a formidable group of businesses which has helped India achieve supremacy in several manufacturing and innovating sectors including Pharmaceutical Industries. When the association was formed, India had business potential for only few million US$. However today over 2.5 Billion US$ worth equipment are being purchased in India.

This association which started with a modest membership of only distributors with an aim to promote Analytical Instrumentation use in Indian Industry by organizing scientific seminars, Research and Academia has grown into a very strong association with many Analytical Instruments manufacturing companies as its members through its Indian offices. Today we are partnering MMI and Analytica for organizing Exhibition and Seminars in India. It is our proud privilege to inform you that JAIMA, Japan and since the year 2022 PITTCON, USA are partnering with us to spread Analytical Instrumentation knowledge.

I am very happy that during my tenure as a President, we could celebrate the completion of 25 years of the association at Novotel Hotel, Hyderabad on 14th September 2023. Dr. S P Vasireddi was our chief guest who expressed what he expects from IAIA in the future. We celebrated the event with felicitating all our Past Presidents who worked hard for the association. Mr. S S Bapat, Dr. G. Ramakrishnan, Mr. S Thyagarajan, Mr. K Venugopalan, Dr. Ashes Ganguly and very young Gautam Rajan have made immense contribution to the industry through this association. We also felicitated Dr. Ramesh Datla, Dr. Ashes Ganguly and Mr. Ranganathan Raghavan, who were bestowed with Life Time Achievement awards. Our supporters IGCC and MMI also were felicitated. We thank the industry members by attending the event in large numbers, making it a successful event and networking with each other. As a part of the Silver Jubilee celebration, we are releasing this Souvenir with great articles from Industry experts and I am sure it will be enriching the knowledge in this space. This "Collector Edition" souvenir has been supported by many members companies with articles and advertisements and I thank all for the same.

During the analytica Anacon 2023 show, we also presented 1 day conference on "Nitrosamines" by industry users and academia. It was a good seminar well received by the participants. I thank all the speakers for their contribution and spending valuable time by even traveling from out station. Finally, I would like to thank Mr. S Thyagarajan for accepting the responsibility to publish the souvenir, his staff, our staff Supriya Shetty for ensuring that we get this ready for release on time.

Wishing you all a very happy new year 2024 in advance..

With best regards

Chandrahas Shetty,

15 November 2023

President IAIA

Indian Analytical Instruments Association

2022-25

Celebrating 25 Years

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Nitin Kabbin

S. Thyagarajan

Advisor, Past President

Indian Analytical Instruments Association

'Amrit Kaal', the 25 yearlong lead up to the India@100 in 2047 is a Vision well-balanced and planned, sculpting the bright roadmap of India's future, nurturing new potential, realizing new resolutions and harnessing new potential to forge ahead with confidence. Emerging as the fastest growing major economy in the world, India is expected to be the third largest global economy soon. At US$ 54.6 Billion, the vibrant Indian pharmaceutical market is leapfrogging to reach US$ 163.1 Billion by 2032 while the total contract research market is poised to double to over US$ 5 Billion in the next five years. Aligning with 'Make in India', India's life science community is adopting a two-pronged strategy including the indigenous development of technology, and indigenisation of technology while India's appeal as an investment destination is gaining momentum as faith in the 'Invest in India' narrative builds, resulting in a thriving 'start-up' ecosystem.

Revolutionizing technology and analytical instrumentation is Digitization and Automation coupled with Artificial Intelligence & Machine Learning. What then ails the Indian Analytical Instrumentation is succinctly explained by Dr. Ramesh Datla wherein while referring to difficulties in sourcing material, complexity in developing indigenous technology etc. he concludes positively on how government policies and collaboration between government - academia and industry could address it. On an upward trajectory to global leadership in pharmaceuticals, hear it from Mr. Mehul Shah on India witnessing sizeable FDI, Mergers and Acquisitions, thereby talent becoming the key to Indian industry achieving Vision 2047! Laying emphasis on 'omics', Mr. Ranganathan Raghavan emphasizes on a cross-disciplinary portfolio-based approach in bio-innovation ensuring a shorter journey from 'molecule to medicine'. In the exponential growth phase is also the Indian CRO, which Dr. Tausif Monif attributes to its cost-effective solutions, conducive regulatory environment and abundant pool of skilled professionals!

Efforts and participation from all sections of society will cause India to rise as shining star in the world economy and a sincere testimony to this fact is this souvenir on 'Market Dynamics of Analytical & Life Science Instrumentation in India'. Providing an all-encompassing Indian perspective as viewed by the champions of the various market segments and instrumentation techniques, every company from Agilent to Waters has shared its narratives of the glorious present and the endless opportunities lying in store for us ahead. My sincere thanks to each and every one of them for their invaluable contribution and also my sincere gratitude to their respective CEOs for permitting such a knowledge exchange.

I also sincerely appreciate the marcom team in Spinco, particularly, – Ajith, Amirtha, Chandrasekar, Partha, Saravanan for their active involvement to bring out this souvenir. Lastly, I profoundly thank IAIA for this opportunity again in collating the articles and presenting the Indian perspective of the market dynamics for today and for tomorrow. Clearly, India is opening its gates to growth, progress and development connoting the era of elixir or 'Amrit Kaal'!

Cheers to another year together and forever to go – Happy New Year!

Warm regards

15 November 2023

S Thyagarajan
Souvenir Editor
Advisor, Past President
Indian Analytical Instruments Association

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A Message from the Pittcon 2024 President

Melinda R. Stephens
Pittcon 2024 President

It is an extreme privilege, in my capacity as the President of the Organizing Committee for Pittcon 2024, that I extend my warm congratulations to the Indian Analytical Instruments Association (IAIA) on the occasion of your 25th Anniversary!

Over these 25 years, the analysis instruments and especially the support your members have provided to the Indian research and manufacturing communities have, in no small way, led to the position of India as a world leader in the production of pharmaceutical and chemical products.

We on the Organizing Committee of Pittcon 2024 are just beginning our direct relationship with IAIA, and we are truly excited to continue our discussions as we work towards stimulating innovation and improving efficiency in chemical laboratories all around the world.

I also wish to congratulate IAIA on another successful India Lab Expo. We at Pittcon understand the huge amount of work that goes into the production of a world-class conference and exhibition and understand that the value we both bring to the scientific community makes it all worthwhile. Thank you for your efforts.

In closing, let me again congratulate the Indian Analytical Instruments Association in its Silver Jubilee Year! Please know of the support of your friends at Pittcon as you begin your next 25 years!

Melinda R. Stephens, Pittcon 2024 President

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AM10:00 – PM5:00

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(planned) **JASIS Conference**
JASIS Hot Topics Seminars
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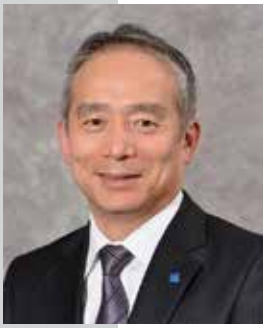
Web Program(planned) **: JASIS WebExpo®**

Organizers: Japan Analytical Instruments Manufacturers' Association, Japan Scientific Instruments Association

Sponsors: Ministry of Economy, Trade and Industry(Japan)/Ministry of Education,Culture,Sports,Science and Technology(Japan)/ Ministry of the Environment(Japan)/U.S.Commercial Service,U.S.Embassy,Tokyo/Others(planned)

Makuhari Messe, Japan
International Exhibition Hall
https://www.jasis.jp/en/



Masayuki Adachi, Dr. Eng.
JAIMA President,

November 10, 2023

Dear Dr. Chandrahas Shetty,

President of IAIA – Indian Analytical Instruments Association

I want to extend our sincerest congratulations on the Silver Jubilee of IAIA – Indian Analytical Instruments Association.

IAIA is one of the most important partners for JAIMA. JAIMA have exchanged invaluable information with IAIA through the Anacon JAIMA Technology Showcase at Analytica Anacon India, as well as mutual visits to JASIS and Analytica Anacon India

We deeply wish IAIA's further development and continuing to enhance solid relationship with IAIA.

Masayuki Adachi, Dr. Eng.
President, Japan Analytical Instruments Manufacturers' Association

IAIA Office Bearers, Committee Members,

Past Presidents and Advisors with the Chief Guest

Nitin Kabbin
- Advisor IAIA

Nostalgia: A History of IAIA

IAIA, is an exclusive professional body was formed in 1996 with a vision to promote, encourage and develop the growth of the Analytical Instruments Industry. The primary objective was to create and share knowledge leading to better relationships between all players.

IAIA aims to be the premier body working towards policy making and planning thus promoting welfare by integrating the entire analytical fraternity. The ecosystem in mid 90s for analytical instruments was not conducive to the players in it. Given the low volumes, the industry had to piggy ride with other associations and shows like Pharmaceutical Congress which focussed on pharma machinery, Chem India mainly on chemical process equipment etc.

Naturally these associations had to take care of the interests of their members, consequently analytical instruments were relegated to the least priority or no priority status in their plans. It started with a call from Mr. Kannan, who was then with Hinditron and mooted the idea of forming an association for the analytical instruments industry.

IAIA was born with the help of 10 founding members, Mr. K Laxminarayan from Merck, Mr. S. S. Bapat, Mr. Ashok Kotwani, Mr. R. K. Pillai from AIMIL, Dr. Ashes Ganguly, then with Netel, Mr. Kannan, Mr. V. S. Rajan, Mr. T. K. Datta, IR Tech, and Mr. Nitin Kabin from the industry. Mr. Rajan drew up the memorandum and the bye laws for IAIA, which was just a 17 page document. These bye laws were changed only once to remove individual membership in the last 25 years, this speaks for the thoroughness of his work.

Mr. S S Bapat was nominated as the first President of the association, though the term of the President is for 3 years, he had to stay put for three terms from 1997 till 2006 to nurture it in its initial years. To his credit Bapat was, and is today, a large hearted person and supported all the initiatives that we rookies could come up with.

Though a fledgling startup, IAIA had big dreams. The role model for the association was none other than the Pittsburg Conference. So, with modest means IAIA organized the first exhibition and conference ANACON at the World Trade Centre, Mumbai in 1997. It was a decent success.

One of the things discussed, quite vigorously, was the earnest money getting stuck in government tenders and how the association could help get it back quickly. It was also being discussed whether membership of IAIA would exempt companies from paying EMDs. On the positive side IAIA could increase its membership based on these discussions.

Dr. P. K. Padmanabhan who too was a founder member, as an individual member. He worked as a bridge between IAIA and BARC and the Indian Society of Analytical Scientists. His contributions in the early days were remarkable and he helped get eminent speakers and delegates from BARC and other institutes.

In the years to come ANACON made a mark for itself and was the go-to show for analytical instruments and technical conference. IAIA became synonymous with its creation ANACON, thanks to the hard work of the early members.

Anacon, as it grew, moved from the World Trade Centre to the Nehru Centre and there on to the BSE Complex. The conferences were top class with eminent speakers from the industry, academia, research and the instruments industry itself, presenting papers and introducing new technologies and applications.

Through the forum of Anacon, IAIA recognized truly outstanding personalities from the industry academia and research. The luminaries included Dr. Kasturirangan, Dr. Anil Kakodkar, Dr. Y. K. Hamid, Dr M. S. Swaminathan, Dr. Anji Reddy, Dr. Deshbandhu Gupta, Dr. R. Chidambaram, Prof. M. M. Sharma, Dr. Rajashekaran Pillai and others.

It was sometime in 2002, Mr. Charanjit Saini, from IGCC, met Mr. Nitin Kabin at his office and suggested why not Anacon join hands with Analytica and thus was born Analytica Anacon. This was an important milestone for IAIA and recognition for Anacon. We were quite glad to associate with IMAG, the international fairs division of Messe Munchen, they bought in their expertise in organizing a show and IAIA bought in the networking with the user industry and experience with the conference. The first Analytica Anacon was held in 2003 in Mumbai and was greatly appreciated. Mr. Kurt Schraudy, heading IMAG and Nikolas Wollman supported the event wholeheartedly. The local partners of IMAG, for the show, was IGCC where we worked with Ms. Soniya Prashar who bought all the professionalism and innovative ideas in organizing an event.

It was then Dr. G. Ramakrishnan was invited to head IAIA. He became the second President in 2006 and brought in lot of energy to the organization with his own characteristic style and flavour. It was under his Presidency that Analytica Anacon moved first to Bangalore in 2006 and then to Hyderabad in 2007. IAIA also started spreading its wings overseas during Ramakrishnan's Presidency.

It was also under his Presidentship that IAIA started recognizing its own and Life Time Achievement awards were instituted.

The first awards were given to Mr. Arun Toshniwal, Mr. Feroze Neterwala, Mr. V. S. Rajan, Mr. Kamlesh Sonawala, Mr. S. Thyagarajan, Mr. K K Ramasubban, Mr. S. G. Bhalerao, Mr. S. S. Bapat, Mr. R. Kannan, and Mr. D. J. Rao.

In the following years the association recognized the contributions of Dr. G. Ramakrishnan, Dr. M. K. Shingari, Mr. T Ravindar, Mr. Gyan Batra of Nucon, Mr. Subash Bagaria Millipore India, Mr. K. Venugopalan and Mr. Nitin Kabin.

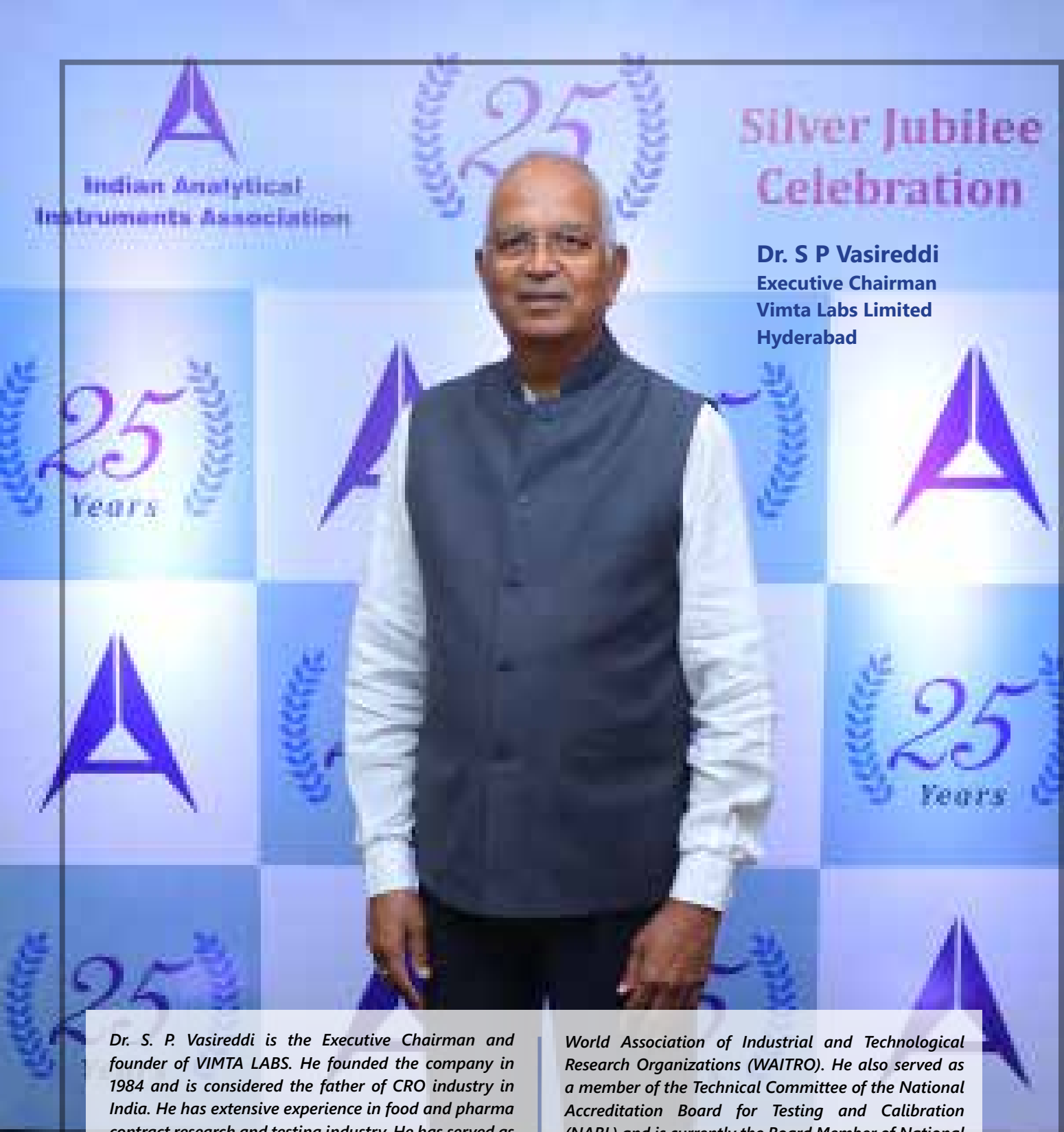
The next President of IAIA was Mr. Thyagarajan and he was totally committed to the association, a great organizer and a prolific publisher. His Presidency saw the publication of the first market information for analytical instruments in India. It was held authentic and even helped a number of MNCs in their India plans. With some financial stability, it was in his Presidency that IAIA acquired its own office in Mumbai, which earlier had moved from Marsap and then to Indtech Instruments office. Mr. Thyagarajan also saw that IAIA was actively engaged with JAIMA and also addressed at their shows about India.

Then Mr. K. V. Venugopalan from Waters and Dr. Ashes Ganguly, Cryogen took over for the next two terms. These terms were studded with numerous programs for members like the GST Seminars, GEM Training, Management Development programs and others. However, it was in Dr. Ganguly's tenure that the JAIMA – IAIA cooperation agreement was signed post his address at the Japanese analytical instruments show.

Then there was a significant shift in IAIA when Gautam Rajan took over, he was the first second generation entrepreneur to take over the reins. A very welcome development as the old makes way for new, we can already see the green shoots in IAIA in the form of Akshay, Arnesh, Rumia and others. Gautam's tenure was marred by COVID but he smartly used it hold a on line seminar on 'Customer Support and Supply Chain Challenges in times of COVID' which was attended by over 1000 people. Ever the captain cool, Gautam, manoeuvred the ship admirably when it was in troubled waters.

There have been many whom we have not able to mention but have strengthened IAIA like Mr. Ravindranath, Mr. D S Raju, Mr. Deepak Parab, Mr. Vipul Chatbar and others, their contributions are equally significant.

IAIA has stood up to the test of times, shown resilience in the head winds it faced and has come out a winner, which this event is a testimony. Today Chandrahas Shetty is the President of IAIA continuing all the programs as in the past. He has been successful in starting a partnership with PITTCON, USA and will have first time a IAIA booth at PITTCON 2024. He also celebrated the completion of 25 years at Hyderabad in 2023.



Dr. S P Vasireddi
Executive Chairman
Vimta Labs Limited
Hyderabad

Dr. S. P. Vasireddi is the Executive Chairman and founder of VIMTA LABS. He founded the company in 1984 and is considered the father of CRO industry in India. He has extensive experience in food and pharma contract research and testing industry. He has served as a Member of Central Advisory Committee of the Food Safety and Standards Authority of India, (FSSAI), Govt. of India, New Delhi (2010-2016). He was a Member of the Research Council of the National Physical Laboratories, India. He was the area-Coordinator of National Conference of Standards Laboratories (NCSL), USA and Regional Representative (Asia-Pacific) of the World Association of Industrial and Technological Research Organizations (WAITRO). He also served as a member of the Technical Committee of the National Accreditation Board for Testing and Calibration (NABL) and is currently the Board Member of National Accreditation Board for Testing and Calibration (NABL). He established a training facility at VIMTA in Public-Private Partnership with UNIDO to provide trainings to developing nations, in the field of Food and Pharma analytical testing and quality systems. He holds a Ph.D in Inorganic Chemistry from Nagpur University, India.

Address by Chief Guest

During Silver Jubilee Celebration of IAIA
Novotel Hotel, Hyderabad | September 14, 2023

Congratulations on the IAIA journey to the Silver Jubilee !

It's a good coincidence with the 'Amrit Kaal' of Indian Economy! I see the Indian Analytical business at another inflection point in the midst of huge opportunities.

Indian Analytical Instrumentation has come a long way to the present state of cutting-edge technologies and compliant systems. Half a century ago analytical instruments were just a prized possession, accessible to a few privileged. It's quite nostalgic to reflect on my first obsession for a Spectrophotometer in 1972 at the Nagpur University, Department of Chemistry. A Spectrophotometer newly imported was maintained like a caged animal, placed in one of the Professor's anti room! A decade later when I founded Vimta Labs, we began to experience analytical instrumentation from Chemitos, Netels, Elicos and so on. Within a year Vimta imported one ICP-AES and that gave the taste of Analytical Technology. Since then, it was no looking back, rest is history. Till the Indian economy got liberalized in 1992 import of Analytical Instruments used to be an ordeal ! One had to learn OGL, IEC, customs duties and so on in addition to analytical science. Several reputed Indian Agents for Analytical instruments have worked hard to anchor global brands in India till the end of last century. Further, Analytical Instrumentation markets began to consolidate with direct presence of principals in India by several leading brands !

Today, an Analyst has a wide choice of Analytical Instrumentation to suit their purpose. Analytical Instruments touch many lives indirectly in assuring Quality of Food, Pharmaceuticals and Environment. We have countless places where Analytical Instruments are deployed. To cite a few:

- NABL accredited Testing Labs – 5021.
- NABL accredited Clinical Labs – 2226.
- Pharma companies – 3000, Manufacturing units – 10500 and so many QC labs.
- Food processing units 41481.

Quality Council of India is driving fast track accreditation of soil testing labs and water testing labs at grass root level. Imagine the proliferation of such labs across the length and breadth of our country!

We have close to 80 CROs operating in the fields of Drug Development, Clinical Research, Pre-Clinical Research, Biologics – well equipped with cutting edge analytical technologies.

And behold !

- Indian Pharma is currently at US$ 60 B, projected to cross US$ 100 B mark by 2028 and reach US$ 130 B by 2030.
- Biologics is expected to touch US$ 25B in the next 5 years.
- Nutraceuticals is already a US$ 10 B business.

Honorable Prime Minister of India has been promoting 'Make in India' concept which is catching up fast.

Indian economy is on the path to be third largest by 2027 and cross US$ 7.2 T by 2030.

Government of India is now encouraging investments in semiconductors/chips and response from global and domestic investors is quite good.

That speaks of never before opportunities.

Chandrayan proved that India can do it.

Name any sector of our economy today, it is on rapid growth.

After all Analytical instruments do play a key role in all sectors of our economy.

How about IAIA responding to 'Make in India' concept ! Assemble global brands of analytical instruments locally and make them more accessible and affordable.

I am sure this decade is also for Analytical Instruments.

Wish you all more successful times in the years to come.

September 14, 2023

Honoring the Past Presidents

SS Bapat

Dr. G Ramakrishnan

S.Thyagarajan
(Received by Janani Thyagarajan)

KV Venugopalan
(Received by Tejinder Singh and Padmini Satish)

Dr. Ashes Ganguly

Gautam Rajan

HALL of FAME 2023

DR. RAMESH DATLA

CHAIRMAN
ELICO LIMITED

- Leads Elico and ELICO Health care Services
- Ph.D in Spectroscopy Instrumentation from SK University; Graduate in Executive Management from MIT, Boston; Master's from Wichita State University and the Indian Institute of Science, Bengaluru.
- Worked in Semiconductor industry, USA for 3 years before joining Elico in 1992.
- Holder of many patents and design copyrights.
- Functioned as the Chairman, of the CII National Committee.
- Past Chairman of the Indo-American Chamber of Commerce - AP and Electronic Industry Association - AP.
- Closely associated with IIT Jodhpur and NIT Warangal, as a mentor.
- Represented India as a member in the French G20-B20 Summit, Mexican G20-B20 Summit, Argentinian G20-B20 Summit, the OECD Conference, GTZ Conference, Gulf Cooperation Council Meeting, USIBC Conference, UKIBC Conference, etc.

LIFE TIME ACHIEVEMENT AWARD

HALL of FAME 2023

LIFE TIME ACHIEVEMENT AWARD

RANGANATHAN RAGHAVAN

CONSULTANT
LIFE SCIENCE INNOVATION COUNCIL
DANAHER CORPORATION

- Masters in Nuclear Physics from University of Madras
- 42 Years in Life Sciences Industry, serving scientists in life science research and working with cutting edge technology solutions.

  1982 - Sales Specialist, LKB Bromma

  1987 - Sales Manager, Pharmacia Biotech

  1991 - Regional Head, Pharmacia United

  1997 - Amersham Bioscience (Amersham & Pharmacia merger)

  2003 - General Manager, Sales - GE Healthcare

  2020 - Cytiva, Heading Cell & Gene Therapy

- Honoured by Society of Structural Biology, University of Delhi for contributions to the research ecosystem.

HALL of FAME 2023

DR. ASHES GANGULY

MANAGING DIRECTOR

CRYOGEN INSTRUMENTS INDIA PVT. LTD.,

- Ph.D from Indian Institute of Technology (IIT), Kharagpur.
- Managing Director of Cryogen Instruments India, a leading supplier of Liquid Helium. Cryogen specializes in Magnetic Resonance (NMR) & Cryofilling.
- Served as President of the Indian Analytical Instruments Association (IAIA) during 2015-18 and represented IAIA in different International Conferences in the USA, UK, Germany, Japan, etc.
- Served as the National Committee Member of the Instruments Division of the Confederation of Indian Industries (CII).
- Past District Governor of Rotary @ Dist 3142 and the recipient of all three major awards of Rotary:

  Service above self,

  Meritorious Service Citation &

  TRF Distinguished Service Award.

LIFE TIME ACHIEVEMENT AWARD

Index

Market Dynamics of Analytical and Life Science Instrumentation in India

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Felicitating Partners

Bhupinder Singh, MMI

Soniya Parashar, IGCC

Development of the Indian analytical instruments industry by IAIA and MMI

Avisha Desai
Business Unit Head - Consumer & Capital Goods
Messe Muenchen India
Mumbai

This article, shares the success story of analytica Anacon India and India Lab Expo and how the collaboration with Indian Analytical Instruments Association has been instrumental in promoting the growth and development of the Indian analytical instruments industry.

Future of Laboratory Technology and Analytical Instrumentation Industry in India

Recent technological advancements and regulatory changes are poised to revolutionize the laboratory technology and analytical instrumentation landscape in the next 5-10 years. Digitization and automation are the key drivers for this transformation.

Technological Advancements

Laboratory technology and analytical instruments will undergo significant technological advancements in the coming years. They will become more compact, portable, and user-friendly, making them easier to use in a variety of settings. Scientists will focus on developing products with higher sensitivity, accuracy, and faster analysis times.

Automation and Artificial Intelligence

Automation will be important to the future of laboratory technology and analytical instruments. Automation and artificial intelligence are being increasingly adopted in laboratories to improve efficiency and productivity. This is leading to a demand for new and innovative laboratory equipment and instrumentation.

> ***The collaboration between IAIA and MMI has been a success story for the Indian analytical instruments industry. analytica Anacon India and India Lab Expo have grown to become two of the most important trade fairs.***

Expansion of Applications

Laboratory technologies and analytical instruments will expand their reach beyond traditional sectors like pharmaceuticals and environmental monitoring into a wide range of new industries. Sectors like food safety, agriculture, forensics, and healthcare will increasingly leverage advanced technologies and instruments for quality control, process optimization, and research.

Emphasis on Quality Testing

Indian consumers are becoming increasingly aware of the importance of quality testing, and this is leading to a higher demand for laboratory services. This is also driving the demand for laboratory equipment and instrumentation.

Focus on Sustainability

In response to growing environmental concerns, the analytical instrumentation industry is moving towards more sustainable practices. This includes developing instruments with energy efficiency features, reduced waste generation, and environmentally friendly materials. Additionally, there is a growing focus on developing instruments for environmental monitoring and pollution control.

Government Initiatives

The Indian government is taking steps to create a thriving scientific and technological ecosystem. Policies that encourage research and development, innovation, and

indigenous manufacturing will propel the laboratory technology and analytical instrument industry forward. Enhanced funding, collaboration, and incentives will further accelerate the adoption and development of laboratory technology and analytical instruments in India.

Impact of R&D on the Laboratory Technology and Analytical Instruments Market in India

R&D is playing a critical role in the growth of the laboratory technology and analytical instruments market in India. Industries such as pharma, F&B, chemicals, environmental testing, and more are investing heavily in research and development. This is leading to increased demand for laboratory technology and analytical instruments from these industries. It is helping to develop new and innovative technologies and instruments that are more innovative, productive, accurate, efficient, and affordable.

R&D is contributing to the development of indigenous technologies and instruments. This is being driven by the government's focus on 'Make in India' in the technology sector. Several Indian companies are now developing and manufacturing world-class products. This is helping to reduce the country's dependence on imports and boost the growth of the domestic laboratory technology and analytical instruments market.

Another important area of R&D is the development of new analytical techniques and methodologies. This is being driven by the need to meet the increasingly stringent testing requirements of various industries. For example, the pharmaceutical industry is required to conduct a wide range of tests to ensure the safety and efficacy of its products. R&D is helping to develop new analytical techniques that can be used to conduct these tests more quickly and accurately.

Collaboration between IAIA and MMI

Messe Muenchen India (MMI) has been collaborating with the Indian Analytical Instruments Association (IAIA) since 2013 to organize analytica Anacon India and India Lab Expo. The collaboration between IAIA and MMI has been instrumental in the massive success of analytica Anacon India and India Lab Expo. The IAIA provides MMI with its expertise in the Indian market and MMI, in turn, provides the IAIA with its global expertise in organizing trade fairs.

The collaboration between IAIA and MMI has been a success story for the Indian analytical instruments industry. analytica Anacon India and India Lab Expo have grown to become two of the most important trade fairs for the industry in the country. The collaboration has also helped to promote the growth and development of the Indian analytical instruments industry.

How analytica Anacon India and India Lab Expo 2024 promote innovation

analytica Anacon India and India Lab Expo bring together international and domestic manufacturers, laboratory users, consultants, and key government officials on one platform, creating an ideal ground for networking and engaging industry professionals for business collaborations.

The 2024 editions to be held in Mumbai and Hyderabad will bring together domestic and international exhibitors to showcase the latest in laboratory technology, analysis, biotechnology, and diagnostics. This will allow industry leaders and experts to witness new technologies

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Over the course of her career spanning more than a decade in the exhibitions industry, Avisha has held various project management roles and responsibilities. She is a domain expert in building new trade fair properties by creating win-win partnerships among industry stakeholders.

Currently, she leads six major trade fairs in India - analytica Anacon India / India Lab Expo, Pharma Pro&Pack Expo, Drink Technology India, Pack Mach Asia Expo, and World Tea & Coffee Expo. Additionally, she also heads the International Business of Messe Muenchen India in South Africa.

Avisha is passionate about women's leadership and holds a position to promote the same at the national level through the Indian Exhibition Industry Association (IEIA).

and learn about the latest trends and developments.

In 2023, the Mumbai edition of analytica Anacon India had over 150 exhibitors showcasing 2,500+ innovative products in a 6,000+ Sq.m of exhibition space. On the other hand, the Hyderabad edition, co-located with Pharma Pro&Pack Expo, had over 366 exhibitors from 14+ countries showcasing 6,000+ products in a 25,000 Sq.m of exhibition space. Alongside displaying the latest technologies, analytica Anacon India and India Lab Expo also conducted knowledge-rich conferences and the popular Buyer-Seller forum.

Scale and Impact of analytica Anacon India and India Lab Expo 2023

Visitor attendance at the Hyderabad edition of analytica Anacon India and India Lab Expo surged this year. This massive attendance in the pharma hub of India once again proved why this is the largest pharma gathering in the region. Additionally, the event witnessed a growth of 40% in the participation of new exhibitors. With ample networking opportunities and invaluable market insights, the event seamlessly brought together stakeholders in the end-to-end pharma and other user industries. Our in-depth understanding of the pharma, laboratory and analytics industries and the ability to build lasting relationships with all stakeholders helped us to create a pulsating marketplace that enabled meaningful interactions and unlocked business opportunities.

Why Mumbai and Hyderabad?

analytica Anacon India and India Lab Expo together form the largest event in Mumbai and Hyderabad for laboratory technologies and analytical instruments. The combined reach of the editions spans the entire country with the Mumbai edition covering the entire west and north regions and the Hyderabad edition covering the entire south and east regions.

With the last edition of Mumbai receiving a tremendous response in two days, the upcoming edition of analytica Anacon India and India Lab Expo will now be held over three days.

Key Highlights of analytica Anacon India and India Lab Expo

Valuable Market Insights

analytica Anacon India and India Lab Expo feature a comprehensive conference program with presentations from leading experts in the field. Businesses can use the conference to learn about the latest trends and technologies in the laboratory industry. This year, the fair offered exciting thought-provoking conferences in collaboration with associations such as the Indian Analytical Instruments Association (IAIA), Federation of Asian Biotech Associations (FABA) and Indian Pharmaceutical Association (IPA). Some of the conference topics included the impact of AI on analytical instrumentation, analytical and lab automation, continuous manufacturing, and more.

Networking Opportunities

The Buyer-Seller Forum at analytica Anacon India and India Lab Expo is a pre-scheduled matchmaking platform that facilitates direct contact between exhibitors and buyers from domestic and international markets. It is a tailor-made opportunity for exhibitors to connect with potential customers. It is a valuable platform for key decision-makers and buyers from the user community to network with suppliers and discuss their procurement requirements. In the 2023 editions, almost 2000 pre-scheduled meetings were held.

Year-round Engagement

India is constantly focusing on improving pharma output and processes through PLIs, stronger R&D capabilities, increased digitization and faster adoption of technologies like automation and robotics, which are the modern-day growth enablers. In line with this, analytica Anacon India and India Lab Expo conduct multi-city roadshows on these topics in key cities such as Hyderabad, Ahmedabad, Chandigarh, Pune, Bengaluru, Chennai, and Vizag. The event witnesses panel discussion and ample networking and is headlined by leading pharma manufacturers and industry experts. The roadshows allow the exhibitors to build prior networks before the main show in Hyderabad.

Co-located Shows

analytica Anacon India is co-located with India Lab Expo and Pharma Pro&Pack Expo. Together these shows attract a large number of visitors from across the pharma, laboratory and analysis industry, including potential customers, partners, and investors. This gives analytica Anacon India an unique opportunity to showcase its products and services to a wider audience and increase its visibility and reach.

What ails Analytical Instrument Manufacturing in India

Dr. Ramesh Datla
Chairman
Elico Limited
Hyderabad

Analytical Instruments play a pivotal role in advancing scientific research, ensuring product quality, and monitoring various critical processes in a range of industries. Researchers across diverse fields use these instruments to obtain precise data that lays the foundation for breakthrough discoveries. They play a fundamental role in sectors such as Life Sciences & Pharmaceuticals, Drug Discovery, Genomics, Healthcare, Agriculture, Environment, Food, Chemicals, Forensics, Homeland Security, etc., helping in improving the quality of life for all living beings.

The Analytical Instrumentation industry is technology intensive, encompassing the understanding of basic sciences such as Physics, Chemistry and Botany in addition to several disciplines of engineering which include electronics (hardware and firmware/software), sensors, detectors, optics, fluidics, mechanics, precision engineering, materials, chemicals, product design, etc. An integrated research ecosystem and competent human resources are essential to address the requirements, to translate into specific technologies.

IAIA estimates the size of the Indian Analytical Instruments Industry at US$3.5 Billion (includes spares and consumables). More than 90% of the market is dominated by imported instruments, manufactured by a few large MNC's, while the balance is served by a large number of small companies.

Deterrents for industry collaboration and innovation

More than six decades back, policy makers in India understood the importance of Analytical Instrumentation due to focus on self-reliance, food security, and importance of Nuclear Energy and Space programs. The government established national research labs to develop these technologies like BARC in 1954 under DAE, CSIO-Central Scientific Instruments Organization in 1959, a CSIR Research Lab, etc. Unfortunately, the technologies thus developed where restricted to only public sector companies (PSUs) and were not allowed to trickle down to the private sector during 60's and 70's. The Department of Science and Technology (DST) started the Instrument Development program in 1975 to address this issue, but unfortunately most of the funding which went to CSIR Labs for development of Instruments was used to buy imported instruments to understand their functionality or reverse engineer them and by the time they developed the prototypes, the technologies were outdated as the departments worked in silos.

Comparatively in the western world, R&D was initially driven extensively by defence and space programs and later supplemented by funding for agriculture and medicine. Preference was given for locally manufactured products for many years. Government budgets were substantial for research programs that integrated government, academia and industrial research in a closed loop program under their respective national technology plans resulting in the establishment of various centres of excellence and generation of wide-ranging IPRs. Consequently, the local industries gained technological superiority and dominated globally.

India similarly created well-established science and technology infrastructure under the CSIR, DAE, DoS and DRDO institutions as well as world-class academic institutions like the IITs and IISc. Despite being well-funded these institutions lacked a good interface with industry, due to the absence of an integrated national technology development program for indigenous instrument development. In fact, an extremely low number of the technologies developed had commercial relevance. In the year 2004, Govt. of India realising the importance of Analytical Instruments, formed a committee under the Indian National Science Academy to study the Instrumentation industry and give their recommendations. While the report studied both Analytical

Instruments and Medical Instruments ecosystem in India, publishing a report '*Strategies and Road Map for development of Instrumentation in India*', nothing much got translated into reality. Unfortunately, even the recent '*Make in India*' initiative, launched in 2014 by the Govt. of India which identified 14 sectors in Electronics for the Govt. to promote, did not include Analytical Instruments. Over the years, India has been denied many high-end technologies under various dual technology control regimes and sanctions.

The number of papers that are published related to Analytical Instrument Designs and related IPR generation, is still very low. There is a general lack of this practice especially in universities and CSIR labs where the division into departments is very rigid. The industry also has not put in much effort in this direction as the culture of collaboration within the scientific community, and research-academia-industry is very poor. The only success witnessed in the scientific community has been in the agriculture, nuclear and space programs which were taken up as mission mode projects.

One of the major hinderances afflicting the domestic market was that the high end of the segment has always preferred pricier imported products while cheaper imports were preferred at the lower end of the segment. Chinese Instruments started entering the Indian market since 2010. Most of the traders started importing under invoiced Chinese products and camouflaged themselves as manufacturers under the 'Make in India' initiative that was encouraged by Govt. of India. In 2016 Government E Marketplace (GeM) was set up as an e-commerce platform to promote products manufactured by MSME's but in reality it became a platform for promoting Chinese products. Several representations were made to the Govt to curtail this practice which finally resulted in GeM recently initiating a vendor assessment procedure. Manufacturing facilities of GeM vendors are now been audited to ensure indigenous manufacturing.

Investments in research and development in addition to a collaborative research ecosystem are needed to ensure a level playing field for the players in this industry. India has seen very few companies allocating big budgets on R&D to develop indigenous technologies except for a few companies like ELICO, Metal Power, etc., in the area of Analytical Instruments and companies, like Transasia, Agappe, Sensa Core, etc., in the area of Clinical Diagnostics and a few PE funded start-ups. However all of them continue to face challenges in moving up the technology chain due to lack of supporting research ecosystem and required talent.

Issues Involved In Development of Analytical Instruments In India – a Case Study

Development of FTIR

FTIR spectroscopy is used primarily for qualitative and quantitative analysis of organic compounds, and for determining the chemical structure of inorganic compounds. Indigenous development of FTIR (Fourier Transform Infrared Spectrophotometer) can serve as best example to demonstrate the issues and intricacies involved in the design and development of a new technologically advanced product in the field of analytical instrumentation in India.

Key Components

- Source – emits the required IR radiation. It consists of *coiled filament* of an appropriate material
- Laser Encoder – serves as a reference. It consists of *HeNe Laser, Visible Detector*
- Interferometer – produces the interferogram. It consists of *Germanium Coated KBr beam splitter, Compensator, Retroreflectors, Moving mechanism (voice coil motor)*

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- Input Output and Collection optics – direct the optical beam - consist of *Off axis Parabolic mirrors*
- Detector – acquires the optical signal and converts to electrical form – consists of IR sensitive *Pyro electric detector or Mercury Cadmium Telluride detector* enclosed in a Dewar for liquid nitrogen cooling or *PbSe detector* depending on the range of operation
- For the validation of the instrument wavelength accuracy standards (NIST traceable standards).

Currently, all the above components have to be imported and any production involving lower volumes results in the product becoming expensive.

Issues involved in developing/sourcing material locally

Efforts were put for indigenous development of some components locally, but it involved a lot of issues and time.

- **Off axis paraboloids:** Efforts have been made to initiate the development of off axis paraboloids at the CSIR labs, which have the best facilities and equipment to do the work.
  - ~ But they are not willing to take up the work until total developmental costs are paid upfront even though they can amortise the cost on the finished components supplied.
  - ~ Price quoted is greater than the price of imported components and therefore the very purpose of going for indigenisation cannot be met.
- **KBr beam splitter:** Steps have been taken for the development of KBr beam splitter at a premier institution, which has all the competencies.
  - ~ Yet the time taken is very high
  - ~ They have failed to reach the required accuracies in component specifications.

Issues involved in sourcing material from other countries

As most of the components cannot be obtained locally, sourcing the material has to be done from other countries. The IR components (IR source, beam splitter, detector) used are difficult to import. Manufacturing companies are supposed to clarify the reasons and purpose for the requirement of the specific materials. Many foreign suppliers do not even supply such items citing that the materials belong to the restricted items list. Moreover, all the advanced optics (Retroreflectors, off axis paraboloids) used in the instrument, need to be imported. The below stated issues plague manufacturers who import material from overseas vendors

- Rates are very high for small quantities
- Overall development cost of the instrument becomes high
- The process is time consuming.

Availability of developmental expertise within the country

Initially both BARC and NPL worked on FTIR instrumentation but there has been no commercial outcome. Many years back a PSU was funded for this project by DST but nothing has been developed so far. In general very little IR instrumentation work is done in the country despite abundant application knowledge available in the country.

Case Study Conclusion

Though this is one example among many, similar issues have been faced in indigenous development of ICP Mass Spectrometers, Raman Spectrometers, XRF, etc. The above case study clearly illustrates the complexities involved in the development of Analytical instrumentation in India. The inadequate ecosystem prevailing in our country has hampered companies in the development of indigenous analytical instruments. It is imperative that centres of excellences are to be developed in various areas of instrumentation for the industry to grow and for the country to possess a strong base for indigenous instrumentation.

The Way Forward

Governments in developed and in most developing countries have shifted their attention towards policies that improve the environment in which businesses function. Impediments to trade and investment are being minimized. The focus of industrial support policies is moving from sectoral support to economy wide measures, such as support for research & development, environmental protection, and promotion of start-ups and growth of new businesses. Government-industry-institution partnerships are encouraged substantially.

India is currently the 5th largest economy and one of the fastest growing economies in the world with an aim to reach the 3rd spot by 2030. As the economy opens up further, there is bound to be an increase in competition. The issues affecting the growth of the industry, need to be addressed urgently, so as to de-bottleneck and help the industry to thrive in the global market. Government and industry must work jointly as partners to minimise and deregulate the operational hurdles and cumbersome procedures which inhibit the smooth functioning and growth of the industry and regulate unfair trade practices more effectively.

To encourage creation of Industry Clusters and Cross Collaboration

"The presence of related and supporting industries is one of the major determinants of a nation's competitiveness. Successful innovation is highly determined by the extent of learning-by-interacting between parties connected together by flow of knowledge, skills, and services' **Philip Kotler**.

Industrial clusters are to be promoted for greater efficiency in terms of resource use and inter-industry as well as inter-sectoral linkages. Production Linked Incentive - PLI Scheme should be extended for high-end Analytical Instruments manufacturing.

To establish Centres of Excellence/ Incubation Centres for Design & Manufacturing

Advanced technology research and development centres for Analytical Instruments need to be promoted and encouraged in order to maintain competitiveness of Indian products in the world market. Developed nations allocate major resources into both private and government research & development, and India needs to emulate this custom. Key technology areas need to be identified and focussed emphasis placed to enable progress.

1. Microelectronic & MEMS Research Centre
2. Sensor Research Centre
3. International Cooperation in basic research and joint developments
4. GITA Program under Department of Science and Technology should be encouraged for Analytical Instruments development
5. Emphasis on developing Intellectual Property
6. Incentivise Cross Collaboration – Industry-Institute, Industry-Industry.

Industry is continuously evolving with advancements in technology such as miniaturization, automation, integration of software for data analysis. Emerging technologies such as nanotechnology and biosensors are disrupting the analytical instrumentation industry influencing the development of newer instruments. Instruments that are used in critical industries such as pharmaceuticals and healthcare should meet stringent regulatory standards for accuracy, precision and reliability. This underscores the criticality of R&D in this industry as it drives innovation resulting in the development of new and improved analytical instruments. Incubation Centres similar to the ones discussed below should be setup for Analytical Instruments

- THub the largest incubation centre in India and TWorks which is the largest prototyping centre in India are located in Hyderabad were setup by Government of Telangana.
- Andhra Pradesh MedTech Zone Ltd., AMTZ, situated in Vizag, is a Government of Andhra Pradesh enterprise mandated to promote manufacture of Medical Devices in India. AMTZ is India's premier medical technology park with common manufacturing facilities and common scientific facilities that include specialized laboratories, warehousing, and testing centres such as the Centre for Electromagnetic Compatibility and Safety Testing, Centre for Biomaterial Testing, Centre for 3-D Printing, Centres for Lasers, MRI Super Conducting Magnets, Gamma Irradiation Centre, Mould & Machining Centre, and many other industrial service centres. AMTZ is one of world's largest medical technology manufacturing cluster with over 100 companies working on research, development and production of life saving medical devices.

To Upskill Talent

An important element in the growth of developed economies has been the contribution of the Knowledge Worker. A Knowledge Worker is an individual with specialised knowledge and skills in the respective field. Analytical Instrumentation being a multidisciplinary, high technology industry requires continuous training of their workers, hence there is a requirement of excellent training centres specialised in relevant fields. The centres of excellence can be defined based on a prescribed set of standards. These can be existing centres in universities, industries, Government or new centres, which meet the necessary requirements. There is a need to evolve uniform standards for training and incentivise Industry-Academia interface.

Conclusion

The Analytical Instrumentation manufacturing Industry is quite fragmented and located in Ambala, Panchkula, Ahmedabad, Mumbai, Nasik, Hyderabad, Chennai, etc. Majority of them have a local focus to meet existing requirements focusing on low end technologies. Very few of them have a global focus, are innovation driven and focused on generation of IP. They sustain their innovation by addressing Indian as well as global markets, producing globally competitive products. Over the last fifteen years, several MNCs commenced their own operations in the country. While initially the focus was on marketing and support activities, they have slowly embarked on setting up Design & Development Centres. Some of these companies have been outsourcing redesigning components/ electronics due to obsolescence to Indian players.

As the '*Start-up*' culture is gaining momentum in the deep tech space, there is a renewed focus in the area of Analytical Instrumentation to enhance the precision, sensitivity, speed and capabilities of instruments used for scientific research and quality assurance in various industries. Several cutting edge technologies are being used to address existing technologies like automation for improving the speed and accuracy of testing. AI/ML is used to improve data analysis and interpretation, allowing for more accurate results. Nanotechnologies are being incorporated in analytical instruments to enhance sensitivity and resolution. Microfluidics is introduced in instruments to reduce reagent consumption and enhance accuracy of results. Internet of Things is used to remotely monitor instruments and collect data for analysis and optimisation. Deep tech has witnessed substantial private equity funding, resulting in a spurt of start-ups in the area of instrumentation –

- Agriculture – Soil Analysis, Crop Analysis, Fresh Produce Analysis
- Environmental Monitoring – Water, Air
- Processed Food - Nutrient Analysis
- Life Sciences – Pharmaceuticals, Nutraceuticals, Sequencing
- Clinical Diagnostics

These start-ups are focusing on developing products by offering total solution to the customers.

As the global analytical instrumentation industry is poised to reach US$55 Billion in revenues, India can play a pivotal role with the right ecosystem and policies to enhance the capabilities of domestic manufacturers to capture a sizeable market share.

The Indian Pharmaceutical Industry: Soaring and Roaring into a Glorious Future

Shri. Mehul Shah
Promoter and Managing Director,
Encube Ethicals
Honorary General Secretary,
The Indian Drugs Manufacturers' Association (IDMA)
Mumbai

The Indian pharmaceutical industry has witnessed significant growth and transformation over the past few decades, establishing itself as the global hub for generic medicines. The industry has contributed to the economic development of the country and has played a crucial role in improving healthcare outcomes in India and worldwide. It is poised for robust growth in the next decade with abundant opportunities for companies of all sizes and capabilities, but also faces various challenges that need to be addressed strategically and timely. The US$50 Billion industry which is split nearly equally between export and domestic markets, is expected to grow at a CAGR of 10% upto 2047 to become US$500 Billion. In the next 5-10 years, it is well set to touch US$73 Billion and US$120 Billion respectively.

In recent times, particularly the last 2-3 years, there has been increased focus and impetus both by the government and pharmaceutical companies to evolve from a volume-driven to innovation-driven industry. It is aptly said that the industry is shifting gears from 'Make in India' to 'Innovate and Make in India'. The Government of India launched a series of policy measures Atmanirbhar Bharat, Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana, Ayushman Bharat, Production Linked Incentives, Promotion of Research and Innovation in Pharma MedTech Sector, and Revised Schedule-M. Many more major and minor reforms are expected in the near future especially on OTC policy, pricing rationalization, and decriminalisation. Many state governments are also offering industry-friendly policies and business-conducive environment to get investments in their respective geographies, source latest technology, generate employment, and increase overall prosperity. The pandemic taught important lesson of having indigenous capabilities and resources for both research and manufacturing.

> ***US$50 Billion industry which is split nearly equally between export and domestic markets, is expected to grow at a CAGR of 10% upto 2047 to become US$500 Billion.***
>
> ***In the next 5-10 years, it is well set to touch US$73 Billion and US$120 Billion respectively***

The industry has a rich history dating back to the early 20th century. Initially, it was largely import-dependent, but post-independence, government implemented policies to encourage indigenous manufacturing. The Patent Act of 1970 played a crucial role by enabling generic drug production, thus giving birth to a burgeoning generic drug manufacturing sector. India's skilled workforce, cost-effective manufacturing, and a vast market base have propelled the industry's growth. Today, the Indian pharmaceutical industry is the 3rd largest globally by volume and 14th largest by value. Key strengths of the industry include a large pool of scientists and engineers, low-cost production capabilities, a broad spectrum of drug manufacturing, and a robust network of research and development (R&D) centres.

With global socio-economic-political trends and dynamics

turning further into favour of India, both Indian and foreign companies being bullish on the capabilities and potential of India, are investing across the value-chain. Investing in manufacturing and marketing capabilities is easier to execute with a reasonable estimate of horizon to expect returns. However, such investments are also easy to emulate by competitors and does not add significant value beyond a threshold parameter for differentiation. Investing in R&D requires courage, conviction, and perseverance. The global as well as Indian industry has been in an acceleration mode for embracing future technologies like high-end analytics, digitisation, and AI/ML for some time now. Everyone wants to churn out new drugs at a high success rate and minimal failures.

With the New Drugs and Clinical Trial Rules in 2019, the clinical trial sector is also growing steadily with many choosing India as one of the trial sites when conducting global clinical trials. It is reported that India's clinical trials market is expected to reach US$3.2 Billion by 2025. The focus on development of new drugs began with the introduction of amendments to India's patent regime in 2005 which permitted patenting of pharmaceutical drugs.

The growing healthcare expenditure in both developed and developing countries is propelling demand for quality and affordable medicines. As populations age and chronic diseases become more prevalent, need for medicines and healthcare products is expected to surge, presenting significant growth opportunities for the Indian pharmaceutical industry.

There is a price erosion in global generics market. The US holds a prominent position as one of the largest export destinations for the Indian pharmaceutical industry, accounting for approximately 30-35% of total formulation exports. In recent years, the US generics market has experienced significant price corrections due to the consolidation of buyers and distributors. The low-cost manufacturing base advantage of India accrued to the industry's benefit in the yesteryears has not much to offer today and tomorrow amidst ever-increasing inflation and supply chain uncertainties. Like the IT industry, low-cost manufacturing may move to other emerging countries in Asia. We have witnessed strategic pivot of many Indian pharmaceutical companies from simple generics to complex generics to innovative drug development. Despite price erosion in the US market, there is immense opportunity as Indian pharmaceutical companies command only US$8 Billion (8%) of the total US generics market which is valued at US$90 Billion.

While many domestic companies are investing substantial amounts in drug research and development, India is still not an innovator's market. The industry average R&D spend hovers around 4-6% of revenues and ~80% industry's total spend on R&D is by the top 5 companies. In contrast, multinational companies invest on an average 15-20% of revenues in R&D and innovation projects. While the industry was one of the first to initiate biosimilar development and launch in the Indian market (e.g., the first biosimilar to Rituximab, Reditux, was launched by Dr. Reddy's in 2007), successes in the developments at scale of next-generation product classes such as gene therapy and specialty drugs have been limited. With collaborative efforts of all stakeholders and commitment to risk-capital, by 2033, India can aspire to build a strong R&D pipeline with 5-7 new molecular entities (NCEs) launched or in their late clinical trial phases and enhance significance

Mehul Shah has over 36 years of entrepreneurial experience in technical and business leadership, building Encube into a global leader in topical formulations. His passion and expertise in topical formulations has defined growth and strategy for Encube. He has devoted his life on topical formulations - research, development, manufacturing, and commercialization and finds excitement in making complex topical formulations accessible to more patients and consumers around the world. He serves on the board of three companies in the US - Intact Therapeutics, Tioga Research, and EnZen Therapeutics. He was awarded Emerging Entrepreneur of the Year at Indian Pharma Awards 2015.

beyond generics, to biologics, and new drug development.

The industry has already embarked on a vision of establishing India's global leadership in pharmaceuticals beyond generics, while driving deeper domestic access and affordability. The unfolding of the consumerisation story in India has revealed a paradigm shift in mindset from illness to wellness and self-care among citizens. A strong domestic market in the branded formulations space has caught attention of all companies. We have seen many brands being switched from prescription to consumer space with the advent of effective marketing strategies and wide distribution networks. Further, India's reputation for providing quality healthcare at affordable prices makes it an attractive destination for medical tourism. The pharmaceutical industry can benefit from the influx of international patients seeking medical treatment in India.

Maintaining high-quality standards and compliance with constantly changing regulations remains a persistent challenge. Stringent regulations can increase compliance costs and impact the industry's competitiveness. The industry has welcomed consultative meetings with regulators in the recent past and has reiterated its commitment for manufacturing and supplying high-quality, safe, efficacious, innovative, and affordable medicines to patients and consumers in India and worldwide. Indian pharmaceutical CEOs met US FDA Commissioner and delegation in Hyderabad on 25th Sep. 2023; it was a very cordial meeting, and everyone appreciated the efforts of the Indian pharmaceutical industry on quality improvements. In Sep. 2023, Government of India proposed Revised Schedule-M. The entire Indian pharmaceutical industry has welcomed this regulatory change and is committed to ensuring adoption and ongoing compliance with determination and discipline.

There are innumerable value-accretion levers to be enabled by the Revised Schedule-M. First, the implementation of new norms, will eventually bring the Indian pharmaceutical industry especially the SMEs to be on par with international standards and thus, make them competent and competitive to enhance their exports as well as adopt global quality frameworks. Second, it will become a positive reinforcement for companies to adhere. The new standards will ensure that Indian pharmaceutical companies follow SOPs, quality control measures, and do not cut corners, improving quality of medicines available in India as well as sold in global market. Third, instituting the same quality across the industry is likely to give confidence to regulators from other countries. Indian FDA's GMP regulation will be globally accepted after PIC/S compliance. It is worthwhile to note that India has highest number (603) of US FDA approved sites outside USA and this number will increase in future as the industry makes sincere and long-term efforts in improving culture of quality and compliance.

The Indian pharmaceutical industry is witnessing sizeable foreign direct investment, M&As, and other strategic partnerships. Domestic manufacturers are looking to tap into international markets by uplifting their quality systems. The number of Abbreviated New Drug Applications (ANDA) to the US FDA filed by Indian companies has been on a modest uptick.

Talent will be key for Indian pharmaceutical industry to achieve Vision 2047. One may have best of infrastructure - it is the people who convert resources into results, and ensures quality, compliance, and performance. Technology is at best an enable to employees working in the shop floor, in the R&D lab, markets, and corporate offices. The Indian pharmaceutical industry that employs more than 3.5 Million professionals directly and contributes to more than 100 Million in indirect employment is focusing on improving talent and upskilling them. About 200,000 pharmacy students graduate every year from various colleges in India. Beyond competitive compensation and career growth opportunities, companies must invest in retaining and nurturing talent for the long-term. The Union Budget 2023 aimed to provide stimulus towards innovation with the announcement of the promotion of a research and innovation programme in pharmaceuticals with a focus on skilling and education in healthcare. The Indian pharmaceutical industry is a knowledge-driven sector with research and innovation being core to the growth. As the industry evolves in terms of people, processes and technology, upskilling and reskilling will be fundamental in the Indian pharma sector to stay competitive and move up the value chain.

The acceleration in adoption of digitization and automation was seen after COVID-19. Earlier, investments in digital infrastructure and technology were the prerogative of the large pharma companies. Now, with technology stacks and solutions being more affordable, customizable, and compliant, even small, and mid-size pharma companies are embracing technology. There are numerous applications across manufacturing, R&D, supply chain, quality, and corporate functions. IT implementation by pharmaceutical companies in India observe compliance with 21 CFR Part 11 of US FDA's regulation on electronic records and signatures. The regulation puts forth both procedural and technical requirements for organisations that have electronic records of data.

Such data are important from a quality and safety standpoint and are used in regulatory submissions.

In marketing, digital platforms and tools provide new avenues for pharmaceutical companies to engage with healthcare professionals, patients, and consumers. Online marketing campaigns, social media platforms, and mobile apps enable targeted advertising, disease awareness campaigns, and patient education. Digital marketing strategies can reach a broader audience, generate leads, and improve brand visibility. In R&D, advanced computational models and AI/ML algorithms can analyse vast amounts of data, identify patterns, and predict drug efficacy. This expedites the identification of potential drug candidates, reduces costs, and improves the success rate of clinical trials.

The world has already noted India's strides in digital revolution with 2 'lighthouse' examples, Cipla and Dr. Reddy's, among the global leaders in adopting fourth industrial revolution technologies. The digital transformation of the Indian pharmaceutical industry can be understood in 3 phases. During phase 1, during 2015-2017, the industry was experimenting and looking for small-scale solutions that were largely standalone systems and applications. 2015 marked the era of 3rd party software, such as Laboratory Information Management System (LIMS), quality management solutions, and data document management solutions. In phase 2, 2018 onwards, we saw increased focus on automating factory floors; more digital initiatives for customer outreach; and an overall rise in the willingness to explore data-driven insights across functions, leveraging data warehouse, data lake, big data, and enhanced data visualisation.

In the third phase, after the pandemic in 2020, we have witnessed extraordinary revolution both in pace and degree of penetration of technologies like AI/ML and IoT. The pandemic catapulted the focus on remote audit, enablement, and execution of processes with regards to manufacturing; compliance check of digital systems; use of analytics and AI; remote desktops; Industry 4.0; digital supply chain; and a commitment towards cloud.

The Indian pharmaceutical industry is forward looking to eclipsing higher pinnacles of success in the next decade. Indigenous manufacturing capabilities for managing variety-complexity-scale, strong intellectual property and regulatory framework, competent talent, technology adoption, policy reforms and support, robust domestic consumption, export competitiveness, strong financial position, and continuous improvement in quality systems and culture, makes the Indian pharmaceutical industry on pathway to phenomenal success. It is only a matter of time that the country's pharmaceutical industry will bring the global leader for quality and innovation. As it continues to innovate, collaborate, and adhere to stringent quality standards, the Indian pharmaceutical sector is set to thrive, contributing significantly to both the nation's economy and global healthcare advancements.

In conclusion, the Indian pharmaceutical industry is ready and deserving for remarkable growth and global influence. Its prowess in producing high-quality, cost-effective drugs, coupled with R&D evolution, positions India as a frontrunner in global healthcare landscape.

The Convergence of Biology and Technology: A New Era of Innovation

Ranganathan Raghavan
Consultant,
Life Sciences Innovation Council (LSIG)
Danaher Corporation

Advances in biological sciences, combined with the accelerating development of computing, data processing, and Artificial Intelligence (AI), are fueling a new wave of innovation that could have significant impact in sectors across the economy, from healthcare and agriculture to consumer goods and energy.

The Biological Science Revolution: A Glimpse from COVID-19

The early response to COVID-19 illustrated the substantial advances in biological science in just the past few years. The speed with which scientists sequenced the virus's genome-weeks rather than months-bore witness to the new world of biology we describe in this report. Sequencing is just the start.

Bio innovations are enabling the rapid introduction of clinical trials of vaccines, the search for effective therapies, and a deep investigation of both the origins and the transmission patterns of the virus.

A New Dawn in Biology

Nearly seven decades after the double helix structure of a DNA molecule was discovered, the world of biology appears to have reached a new phase of growth. A flurry of recent innovations-such as CRISPR-Cas9 to edit genes and stem cell advances to reprogram cells-are providing new understanding, new materials, and new tools, as well as lower costs. The science is so advanced, for example, that in 2016, a Human Cell Atlas project was kicked off to create comprehensive reference maps of all human cells as a basis for research, diagnosis, monitoring, and treatment. Moreover, as a result of the scientific advances, a growing number of applications are emerging from the lab and being put to commercial use.

Biological Innovations and Human Health

Human health is one of the most significant domains where biological advances are being applied. Biology is already helping save lives through innovative treatments tailored to our genomes and microbiomes. In the future, we estimate that almost half of the global disease burden could be addressed through applications that are scientifically conceivable today. Moreover, many of the innovations born of these bio innovations contributed to the global response to the SARS-CoV-2 pandemic in early 2020.

The Four Arenas of Biological Innovation

A wave of innovation is being enabled by advances in biological sciences accelerated by developments in computing, data analytics, machine learning, AI, and biological engineering.

Innovations are flourishing in Four Key areas

1. Biomolecules
2. Biosystems
3. Bio-machine interfaces
4. Biocomputing

Major breakthroughs in each of the four arenas are reinforcing one another. In biomolecules and biosystems, advances in omics and molecular technologies-the mapping and measuring of molecules and pathways within cells, and engineering them-are enhancing our understanding of biological processes, as well as enabling us to engineer biology.

For example, CRISPR technology allows scientists to edit genes more quickly and precisely than previous techniques. Advances in bio-machines and biocomputing both involve deep interaction between biology and machines; it is becoming increasingly possible to measure neural signals and power precise neuroprosthetics. It is now also possible to store the world's wealth of data using DNA-by some measures one kilogram of DNA could hypothetically store all current data in the world.

Data Revolution in Biology

Worldwide DNA sequencing now creates huge volumes of biological data every year. These technical advances, such as lower-cost sequencing or high-throughput screening, have helped lower the costs of entry, accelerate the pace of experimentation, and generate new forms of data to help us better

understand biology. Advances at the single-cell level, such as single-cell imaging tools and single-cell ribonucleic acid (RNA) sequencing, are allowing scientists to build increasingly high-resolution maps of cells, which can be a basis for research, diagnosis, and treatment. Increasingly, the ability to understand and engineer biological processes exists across a variety of dimensions.

Biological Transformation Across Industries

New biological capabilities have the potential to bring sweeping change to economies and societies. The effects will be felt across value chains, from how R&D is conducted to the physical inputs in manufacturing to the way medicines and consumer products are delivered and consumed. These capabilities include the following: - Biological means could be used to produce a large share of the global economy's physical materials, potentially with improved performance and sustainability.

Significant potential exists to improve the characteristics of materials, reduce the emissions profile of manufacturing and processing, and shorten value chains. Fermentation, for centuries used to make bread and brew beer, is now being used to create fabrics such as artificial spider silk.

Biology is increasingly being used to create novel materials that can raise quality, introduce entirely new capabilities, be biodegradable, and be produced in a way that generates significantly less carbon emissions. Mushroom roots rather than animal hide can be used to make leather.

Plastics can be made with yeast instead of petrochemicals. - Increased control and precision in methodology is occurring across the value chain, from delivery to development and consumption with more personalization.

Precision in Methodology

Advances in biological sciences have made R&D and delivery processes more precise and predictable; the character of R&D is shifting from discovery by accident to rational design. Increasing knowledge of human genomes and the links between certain genes and diseases is enabling the spread of personalized or precision medicine, which can be more effective than the one-size-fits-all therapies of the past.

Precision also applies to agriculture, where insights from a plant or soil's microbiome increasingly can be used to optimize yield as well as to offer consumers with, for instance, personalized nutrition plans based on genetic tests.

Engineering Organisms

The capability to engineer and reprogram human and non-human organisms is increasing. Gene therapies could offer complete cures of some diseases for the first time. The same technical advances that are driving capabilities that improve human health can be used to introduce valuable new traits that, for instance, improve the output or yield of non-human organisms like microbes, plants, and animals.

Crops can be genetically engineered to produce higher yields and be more heat- or drought-resistant, for instance. By permanently genetically altering the vectors spreading disease

Ranganathan, born in Chennai, has a Post Graduate Degree in Nuclear Physics. He started his career in Sales in 1982 for LKB Bromma, Sweden and subsequently moved to Pharmacia, post the merger between Pharmacia-LKB in 1987. In 1991, he shifted to Delhi as Regional Head for Pharmacia Biotech, establishing a strong foundation for their products in life science research. In 1997 he was promoted as National Commercial Manager, when Amersham and Pharmacia merged. Later on in 2003 he became part of GE Healthcare when Amersham was acquired by GE Healthcare and was instrumental in growing business of GE Healthcare multifold. In 2020, after completing a long stint in GE Healthcare, he moved to Cytiva, a group company of Danaher Corporation, heading the Research, Cell & Gene Therapy businesses. He is serving as Consultant for the Life Science Innovation Council since January 2023 at Danaher. He has been honored by Society of Structural Biology, University of Delhi for his outstanding support to the research ecosystem.

(such as mosquitoes), gene drives could be used to prevent vector-borne diseases, including malaria, dengue fever, schistosomiasis, and Lyme disease, although they also come with ecological risks.

R&D Revolution

New methodologies using automation, machine learning, and proliferating biological data are enhancing discovery, throughput, and productivity in R&D. Biology and computing together are accelerating R&D, thereby addressing a productivity challenge. An explosion of biological data due to cheaper sequencing can be used by biotech companies and research institutes that increasingly are using robotic automation and of the four, innovators are most active in the field of biomolecules, which is developing the fastest judging by the number of active startups and amount of funding.

Biosystems, which is closely related to biomolecules, is the second-most-active area.

Biomachine interfaces, or connecting nervous systems to machines, are at a relatively early stage, but activity is increasing among established technology companies, academic research labs, and emerging startups.

Biocomputing is arguably the least developed of the four key arenas.

Biomolecules: This area groups biological sciences that are collectively known as omics and molecular technologies. Omics consist primarily of mapping and measuring various molecules and pathways within cells. Molecular technologies engineer such molecules and pathways.

Of all the omics, genomics is the most technologically advanced; applications that measure and map genes and then engineer them are in full development and use. However, the genome is by no means the entire story; other omics-particularly epigenomics-are needed to understand phenotypes (characteristics that manifest) by studying a number of steps such as what genes are expressed, at what level, and what environmental factors have an influence.

> ***The world of biology appears to have reached a new phase of growth. A flurry of recent innovations - such as CRISPR–Cas9 to edit genes and stem cell advances to reprogram cells - are providing new understanding, new materials and new tools to advance diagnostics and healthcare administration.***

While the genome is largely static, other omics are dynamic and vary across time and in different environments. Work on these other omics is increasing. In particular, analysis and engineering of RNA (transcriptomics) and proteins (proteomics) are accelerating. The science behind each omic varies in maturity, and accordingly, the amount of funding and the volume of publications in each area vary widely.

The cost of mapping, sequencing, and analyzing the genome has fallen even as the speed has increased in recent years. The cost of DNA sequencing is declining at a quicker pace than Moore's Law, which holds that the processing power of computers doubles roughly every 18 months for the same cost. The sequencing of the first human genome cost almost US$3 billion. In 2019, the cost was less than US$1,000. Within a decade, the cost could be less than US$100. DNA testing is also increasingly sensitive, able to detect even fragments circulating in the blood. A fall in the cost of computing has enabled next-generation DNA sequencing, a range of modern techniques in which millions or billions of DNA strands can be sequenced in parallel, and then assembled into a single sequence. This assembly is needed because it is not possible to sequence a whole genome directly in one read using current sequencing technologies. Current so-called 'Third Generation Sequencing' is under development to enable sequencing an entire strand of DNA without breaking it into smaller strands.

In the wake of the COVID-19 outbreak, scientists were able to sequence and publicly share the whole coronavirus genome just a few weeks after the first cases were reported in December 2019. By comparison, during the SARS outbreak in 2002, full genome sequencing of the virus took more than five months after the first reported case.

A similar dynamic interaction may take place between cheaper computing and the other omics as they develop. Advances in bioinformatics and AI mean that it is possible to mine much more information and insights from omic data sets. AI is enhancing these techniques. Bioinformatic techniques are needed to analyze and interpret data generated from omics, and AI promises to further enhance our understanding of all omic data sets and thereby enable a proliferation of applications.

These complementary technologies have already enabled computer-intensive research such as genome-wide association studies (GWAS) that find associations between a particular human trait and variation in a genetic sequence throughout the genome across a large population. GWAS are responsible for a wave of discoveries about the risk factors for common diseases.

In a GWAS, researchers use computers to compare genomes across large populations, including some people who have a particular disease and many who don't. Subject groups that are otherwise well matched in aspects such as age and gender are sequenced to find areas of consistent differences, that is which genes are associated with which traits. If such areas are discovered, this helps scientists to zero in on parts of the genome that are responsible for the risk of disease.

Genomic engineering technologies have shown exponential improvement. Technologies in DNA synthesis are developing. Although the ability to synthesize DNA *de novo* is limited in comparison with sequencing DNA, the gap is closing.

New inkjet- and semiconductor-based technologies have reduced costs and, at the same time, increased the accuracy of microarray-based DNA synthesis. Synthesized DNA strands can now be longer and cheaper than ever before. At the same time, DNA editing is advancing rapidly. It is now possible to edit genomic sequences-program life, if you will-more efficiently and effectively through tools such as CRISPR applied to human, plant, animal, and microbial DNA.

The Power of CRISPR

Research teams around the world developed the technology, which is within the capabilities of a basic biology lab to use. CRISPR is relatively precise and cost-efficient because it requires only one endonuclease (an enzyme that breaks down a nucleotide chain into two or more shorter chains by cleaving the phosphodiester bond within a polynucleotide chain) and a short single strand of gRNA (guide RNA).

The first human clinical trials of CRISPR were held in 2016 by researchers at Sichuan University in China who injected a cancer patient with cells containing CRISPR edited genes. In 2016, 1,097 CRISPR patents were issued. By 2017, the number of CRISPR patents had risen to 1,303. It took only two years to develop the science for CRISPR and only one to commercialize this approach. Recent advances have made it possible to modify multiple target sites-about 25-within genes in a cell simultaneously. These advances have also set off a new generation of bioengineering research in the field of synthetic biology, which has provided the basis for many of the technologies covered in the biomolecules area.

Mass spectrometry underlies a number of the non-nucleotide (DNA, RNA) omics, but thus far advances have not been as rapid. Scientists face a number of challenges. More sensitivity is needed. Today, proteins, metabolites, and lipids cannot be amplified for detection like DNA or RNA, meaning that differences are much harder to detect.

Conclusion

Businesses should consider how to take advantage of bio innovation, including adapting strategies. Companies operating in virtually every sector of the economy could be affected by bio-innovations as applications in one domain have knock-on effects on upstream, downstream and adjacent sectors. In the case of applications in agriculture, aquaculture, and food, there will be spillover into food retailing and transportation, for instance. Moreover, entire value chains could be transformed. In the case of materials, for instance, with a shift from plastic to bio-based plastic packaging increasingly desired by consumers, the packaging industry could look very different.

The meat value chain is another case in point. In the traditional meat production value chain, animals are bred, fed, slaughtered (fished), and processed prior to distribution, while the value chain for cultured meat is highly compressed, involving only tissue sampling, media production, and live-tissue cultivation of cells into meat-often done by the same company.

Many companies will likely need to adapt their business strategies. Given the uncertainty and evidently varied timing of adoption for different applications, companies should consider a portfolio-based approach toward investments in bio innovation that embraces applications that could become commercially viable in the relatively short term, and those that could deliver impact further out. By its nature, bio innovation is crossdis-cipline-embracing not only biological science, but also computing, AI, data analytics, and engineering. As such, it is unlikely that any business existing today can go it alone. Therefore, it's important to master the confluence of disciplines in bio innovation with the right mix of talent and collaborations. Although large companies could develop the full range of necessary capabilities in-house, it is likely to be quicker and more effective to 'buy in' what they need through mergers and acquisitions, and partnerships. Small companies specializing in particular scientific fields are already collaborating with large incumbents with the market clout to commercialize at scale. As in the Digital Revolution, companies interested in the opportunity of bio-innovation should consider platform-based business models that can seize cross-sector opportunities, reduce marginal costs, and drive combinatorial innovation by leveraging growing biological data. There are already platforms that offer farm-management systems and cloud-based platforms that analyze huge amounts of genomic data to inform breeding decisions. Among other aspects to consider are the range of opportunities for more personalized and precise offerings enabled by growing amounts of biological data, and innovative revenue models that could help accelerate diffusion. Subscription-based offerings to generate revenue are becoming more common in personalized products and services based on genome and microbiome profiles.

To conclude, Biology has finally arrived in full form and we expect various companies will embark on the journey to make healthcare affordable, accessible. We expect AI and MI will work in tandem with the domain experts of Biology to bring the required medicine / therapeutics / vaccine in much shorter times and will also bring down cost so that the majority of the population could benefit from these activities. The pace of innovation in biomanufacturing is creating an opportunity to rapidly adopt cutting-edge manufacturing approaches while creating synergy with the ecosystem through partnerships and new investment.

Instruments for Diagnostics: Focus on Automation and Modernization

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The journey of *In-vitro* Diagnostics (IVD) has been nothing short of awe-inspiring, spanning millennia of human curiosity and innovation. From the days of Hippocrates in 300 BC, who first championed the examination of urine for diagnosing diseases, to our cutting-edge, automation-driven present, IVD has evolved into a realm where science meets precision.

In today's dynamic landscape, researchers eagerly harness the power of analytical prowess. They zealously chase attributes like unerring linearity, pinpoint accuracy, meticulous precision, ultrahigh sensitivity, razor-sharp specificity, the ever-elusive matrix effects and the challenge of nixing carryover, all while dancing with the intricacies of calibration. But there's more to this riveting tale. The IVD field also grapples with formidable forces, like economic pressures that push the boundaries of efficiency and cost-effectiveness.

As we stand at the precipice of IVD's future, the excitement is palpable. With each innovation, IVD propels humanity forward, closer to the dream of swift, accurate diagnoses, paving the way for healthier, happier lives.

> ***Among the stars of new technological innovations in diagnostics are Next-Generation Sequencing (NGS) and Mass Spectrometry (MS). NGS, a marvel of genomics, has unveiled the intricate genetic tapestry of diseases, offering insights into personalized medicine and cancer diagnostics. Meanwhile, MS has ushered in a new era of molecular analysis, providing unprecedented capabilities in identifying and quantifying molecules with exceptional precision.***

India Market Scenario

The diagnostic industry in India has experienced remarkable growth in recent years. The pandemic compelled companies to adapt to increased demand for testing, swift results, and precise diagnosis, pushing them beyond their comfort zones. The integration of technology has further illuminated the prospects of diagnostic companies, alongside the expanding middle class, heightened awareness of preventive healthcare, and greater healthcare spending.

The surge in chronic, lifestyle, and communicable diseases has also had a positive impact on the diagnostic industry. Collaborations between corporations, multinational companies, hospitals, and diagnostic centres for employee healthcare check-ups have bolstered the market. With high-quality diagnostic services available at affordable rates, India is swiftly establishing itself as a hub for medical tourism, attracting patients from around the world seeking cost-effective, hassle-free, and top-notch treatment options.

Given these trends, it is unsurprising that studies project this sector to maintain an annual Compound Annual Growth Rate (CAGR) of 11-12 percent, poised to deliver unprecedented value in the coming decade.

Globally, the diagnostics sector has changed dramatically with the inclusion of artificial intelligence (AI), automation, robotics, point-of-care (POC) testing data analytics, the integration of electronic health records, and quality control. In India, the diagnostics space is a growing sector with an annual CAGR of

11–12%. The sector has witnessed exponential growth since the onset of the COVID-19 pandemic.

A Journey Through Instruments and Technologies

In the sphere of IVD, a fascinating spectrum of instruments, techniques, and technologies has emerged, illuminating the path from conventional methodologies to the cutting-edge wonders of automation. This journey represents a relentless pursuit of accuracy, speed, and precision in the quest to decode the secrets of human health.

At the foundation of IVD lies an array of conventional instruments such as microscopes, culture plates, and simple biochemical assays. These stalwarts have served as the backbone of diagnostics for centuries, offering valuable insights into infections, cell abnormalities, and basic blood chemistry.

Stepping into the modern era, automation has taken centre stage. Automated analyzers, including clinical chemistry analyzers and hematology analyzers, have revolutionized the diagnostic landscape. These high-throughput systems enable rapid and accurate testing of blood, urine, and other body fluids, significantly reducing human error and enhancing efficiency.

Among the stars of this technological revolution are Next-Generation Sequencing (NGS) and Mass Spectrometry (MS). NGS, a marvel of genomics, has unveiled the intricate genetic tapestry of diseases, offering insights into personalized medicine and cancer diagnostics. Meanwhile, MS has ushered in a new era of molecular analysis, providing unprecedented capabilities in identifying and quantifying molecules with exceptional precision.

This exploration of IVD instruments and technologies promises an exhilarating journey, where the convergence of tradition and innovation continues to redefine the boundaries of what is possible in the diagnosis and treatment of diseases.

The Diagnostics Revolution in India: MS and NGS Leading the Way

India's diagnostic landscape has undergone a remarkable transformation in recent years, driven by advances in Next-Generation Sequencing (NGS) and Mass Spectrometry (MS) technologies. As these cutting-edge techniques gain acceptance, private diagnostic labs like Thyrocare Technologies, Neuberg Supratech, Pathkind, Yoda Lifeline Diagnostics, Navigene, etc., are spearheading the change, while government and institutional setups such as the Institute of Child Health in Chennai, Kasturba Medical College & Hospital in Manipal, Christian Medical College in Vellore, etc., are also embracing the diagnostic revolution.

India's diagnostic market is booming, driven by a rising healthcare-conscious population and increasing disease burdens. According to recent statistics, the Indian diagnostics market is expected to reach a staggering US$32 billion by 2030. NGS and MS technologies have played a pivotal role in this growth, offering accurate, efficient, and cost-effective diagnostic solutions.

Private diagnostic giants like Thyrocare Technologies, Neuberg Supratech, Pathkind, Yoda Lifeline Diagnostics, Navigene, etc., have been quick to recognize the potential of NGS and MS. They have integrated these technologies into their operations, enabling faster and more precise diagnostics. Government and institutional setups have also embraced NGS and MS. The Institute of Child Health in Chennai utilizes LC-MS for Newborn Screening, enabling early diagnosis and treatment of Inborn Errors of Metabolism. Similarly, Christian Medical College in Vellore employs LC-MS to advance research and improve patient care.

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Fig. 1: 300 BC Hippocrates examination of urine to diagnose diseases

These technologies have added immense value by enhancing diagnostic accuracy, speeding up results, and facilitating personalized medicine. NGS has proven vital in identifying genetic predispositions to diseases, while MS's insights are invaluable in disease monitoring and treatment planning.

The acceptance of MS and NGS in India's diagnostic landscape represents a significant leap forward in healthcare. These technologies are driving the market's growth, improving patient outcomes, and enabling a more precise and personalized approach to diagnostics and treatment. As India's healthcare sector continues to evolve, MS and NGS will undoubtedly play a central role in shaping its future.

Elevating Diagnostics to New Heights: The Power of Mass Spectrometry

In the ever-evolving realm of *In-Vitro* Diagnostics (IVD), the marriage between advanced mass spectrometry technologies and medical science has given rise to groundbreaking innovations. Liquid Chromatography Mass Spectrometry (LC-MS), Gas Chromatography Mass Spectrometry (GC-MS), Inductively Coupled Plasma Mass Spectrometry (ICP-MS), Matrix-Assisted Laser Desorption/ Ionization Time-of-Flight Mass Spectrometry (MALDI-TOF), and Quadrupole Time-of-Flight Mass Spectrometry (Q-TOF) have emerged as the titans of analytical precision, adding immense value to human diagnostics while aligning seamlessly with recent trends in healthcare.

LC-MS

The Precision Pioneer

At the forefront of this diagnostic revolution stands LC-MS, a fusion of liquid chromatography and mass spectrometry. Its unparalleled ability to separate and quantify compounds within complex mixtures has transformed the diagnosis and monitoring of diseases, from diabetes to drug toxicity. Recent trends in IVD have emphasized personalized medicine, and LC-MS has risen to the challenge. By analyzing patient samples at the molecular level, LC-MS allows for tailored treatments based on individual metabolic profiles, optimizing therapeutic outcomes while minimizing side effects. Moreover, LC-MS plays a pivotal role in therapeutic drug monitoring, ensuring that medication levels in patients remain within the therapeutic window.

GC-MS

Unveiling the Secrets of Volatiles

In the arena of volatile and semi-volatile compound analysis, GC-MS reigns supreme. It's a linchpin in identifying substances like drugs, pesticides, and environmental toxins. Recent IVD trends have spotlighted the importance of environmental and occupational health, where GC-MS proves its mettle by uncovering traces of contaminants that might affect public well-being. In the clinical realm, GC-MS plays a vital role in toxicology, detecting drugs of abuse, and therapeutic drug monitoring with unsurpassed sensitivity and specificity.

ICP-MS

The Elemental Detective

In the world of trace element analysis, Inductively Coupled Plasma Mass Spectrometry (ICP-MS) emerges as a game-changer. Its ability to detect and quantify elements at ultra-low concentrations has found applications in clinical diagnostics, particularly for heavy metal poisoning assessments and the monitoring of essential elements. This aligns perfectly with the current trend of heightened environmental awareness and the recognition of the health impacts of trace elements.

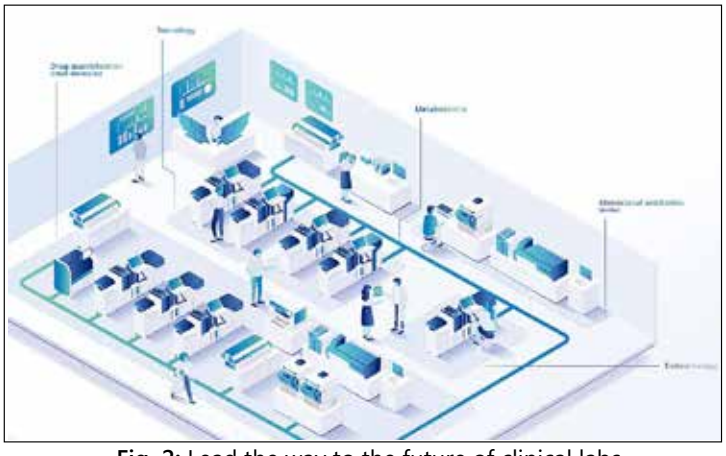

Fig. 2: Lead the way to the future of clinical labs

MALDI-TOF

The Microbial Whisperer

Matrix-Assisted Laser Desorption/ Ionization Time-of-Flight Mass Spectrometry (MALDI-TOF) has redefined microbial identification in clinical laboratories. Its rapid and accurate characterization of microorganisms has revolutionized infectious disease diagnostics. The recent trend towards antimicrobial stewardship programs, aimed at curbing antibiotic resistance, leans heavily on MALDI-TOF's ability to swiftly identify pathogens and their susceptibility to antibiotics. This not only improves patient outcomes but also contributes to the global fight against antibiotic resistance.

Q-TOF

Precision Redefined

Quadrupole Time-of-Flight Mass Spectrometry (Q-TOF) epitomizes precision in both qualitative and quantitative analysis. Recent trends in IVD emphasize the importance of comprehensive biomarker discovery for diseases like cancer. Q-TOF enables researchers to explore the proteome and metabolome with unprecedented accuracy, facilitating the discovery of novel biomarkers and therapeutic targets. Its high-resolution mass analysis is particularly valuable in identifying complex molecules, promising breakthroughs in understanding disease mechanisms and treatment development.

Recent Trends in IVD and Mass Spectrometry: A Perfect Synergy

Recent trends in IVD have pushed the boundaries of precision, personalization, and speed. Here's how these advanced mass spectrometry techniques align with these trends:

1. **Personalized Medicine:** Mass spectrometry, particularly LC-MS, Q-TOF, and MALDI-TOF, allows for the profiling of individual metabolomes and proteomes. This personalization extends to drug therapy, where LC-MS ensures that medications are administered at optimal levels for each patient.

2. **Early Disease Detection:** The high sensitivity and specificity of these mass spectrometry techniques make them invaluable for early disease detection. Whether it's identifying cancer biomarkers or detecting infectious agents, these tools enable faster and more accurate diagnoses.

3. **Environmental Awareness:** GC-MS and ICP-MS are instrumental in environmental and occupational health assessments. The growing emphasis on environmental responsibility and the health impacts of contaminants dovetails seamlessly with their capabilities.

4. **Antimicrobial Stewardship:** MALDI-TOF has become a linchpin in the fight against antibiotic resistance, aligning with the global trends toward more judicious use of antibiotics.

5. **Biomarker Discovery:** Q-TOF's high-resolution mass analysis empowers researchers to delve deeper into the human proteome and metabolome, offering exciting prospects in biomarker discovery for various diseases.

The integration of advanced mass spectrometry techniques into In-Vitro Diagnostics has ushered in a new era of precision and personalization. These instruments not only add significant value to human diagnostics but also align perfectly with the recent trends driving healthcare towards a future where diagnoses are swift, treatments are tailored, and public health and environmental concerns are addressed with meticulous care. As technology continues to evolve, the synergistic relationship between mass spectrometry and IVD promises to unlock even greater possibilities in the realm of human diagnostics.

Fig. 3: CLAM-2040

Shimadzu CLAM-2040: The Innovation Revolutionizing In-Vitro Diagnostics

Precision is paramount in diagnostics, and the CLAM-2040 excels in this regard. While mass spectrometry, including LC-MS, GC-MS, ICP-MS, and Q-TOF, has long been a stalwart in the field of In-Vitro Diagnostics (IVD), a transformative addition to the diagnostic arsenal has arrived: the Shimadzu CLAM-2040 (Clinical Laboratory Automated Module). This sophisticated instrument, designed and engineered by Shimadzu, is poised to redefine the way diagnostic laboratories operate and is right in step with current IVD trends.

Simply uncap sample collection tubes (or specialized sample cups)

and place them into the system. Select the appropriate method from the touch screen, and then the CLAM-2040 performs the next steps automatically: dispensing the sample onto the specialized filter vial, adding reagents, shaking, heating, filtering, and transferring the extracted sample to the LC-MS system autosampler. The LCD touchscreen allows for rapid control through the dedicated user-oriented software. Containers for liquid waste and filter waste reduce the infection risk and ensure operator safety. Easy access to all system automated parts, consumables, and waste also allows for easy maintenance over time.

The CLAM-2040 and LC-MS instrument accompany the analytical workflow and improve your overall throughput by drastically reducing the sample preparation time. Additionally, the CLAM-2040 has the capability to prepare up to 3 samples simultaneously to further optimize your routine. While manual or semi-automated sample extraction will deliver one result every 12 to 60 min, the CLAM-2040 and LC-MS, under optimized conditions, will deliver up to one result every 2.6 min.

High efficiency and high comfort of CLAM-2040

Improved Efficiency. Higher throughput at a lower cost by reducing manual operations. Save time on intensive user training with an open and easy access system.

Multiplex Analysis. Associated with the CLAM-2040, Shimadzu's LC-MS technology enables you to analyze several compounds simultaneously, saving time and reducing overall costs.

24 Hour / 7 Day Capability. Run samples at night and on weekends. Add samples and consumables continuously with the option to submit priority analysis requests for urgent samples.

Higher User Comfort. Decrease in manual operation helps prevent end-user errors. Controlled safety creates peace of mind, and the intuitive software makes it effortless to run samples.

Shimadzu has always attached great importance to providing the best solutions while maintaining the highest possible flexibility for the operator and providing products of great robustness. These key advantages are at the heart of our developments and in all our products. Here too, the CLAM-2040 surpasses these values to give reliable results and increased confidence.

Use Any Application Of Your Choice

- Compatible with a wide range of Shimadzu methods.
- Supports reagents.
- Compatible with third-party reagents.
- Easily transfer your laboratory-developed tests (LDT).

Freedom To Change

- Methods can be optimized and modified.
- New methods can be freely added without the need for Shimadzu intervention.
- Creating your in-house method (LDT) is possible at any time.

Flexibility

- Freedom to choose your LC-MS configuration and to evolve it at will.
- A wide range of purifications available, such as online solid phase extraction (SPE).
- Various sample and reagent containers available to meet the diversity of routine needs.
- The LC-MS system can be used independently.

Operational Connectivity

- Connect to your laboratory information system at any time.
- Connect your LC-MS system to online automation when necessary.

Robustness

- Standardized workflow reduces variability in sample results.
- Includes the latest quality control functionalities.
- Built to handle high throughput of biological samples.
- Consistent results over time reduces calibration frequency.

To meet your required sensitivity, you are free to choose your LC-MS/MS system by selecting one of our triple quadrupoles, from the LCMS-8040 (not shown below) to the LCMS-8060NX. You can change your MS system at any time. For your most exigent screenings, high resolution is also available with our time-of-flight systems (Q-TOF). These options ensure maximum flexibility.

Intuitive Software

- Easy to pilot with no need for expertise or training.
- Easy to optimize and modify existing methods.
- Easy to configure your own methods.

Easy Reagent Management

- Reagent vials of 3 different volumes for maximum adaptability and flexibility: 1.5 mL, 6 mL, or 12 mL.
- Free configuration of your reagents (commercial or in-house).
- Clear display of available reagents and remaining usage count.
- Automatic detection of missing reagents before starting analysis.

Straightforward analysis

- Simply scan your sample ID using the barcode reader, select the analysis method, and press start.
- The CLAM-2040 will perform the next steps automatically.

Easy Data Review

- Easy visualization of calibration

results (precision and accuracy).

- Easy visualization of quality control results (precision and acceptance range).
- Data alerts when results are out-of-specification.
- Easy review of quantitative results (concentrations).
- Possibility to check individual chromatograms when needed.
- Direct communication with LIS for data reporting.

The CLAM-2040 is a game-changer, boasting an impressive range of capabilities. At its core, it's an integrated, automated liquid chromatography-mass spectrometry (LC-MS) system that streamlines the entire analytical process. This instrument handles sample preparation, injection, separation, mass spectrometry analysis, and even data reporting, all within a single, compact module. Its unparalleled efficiency frees up valuable time for lab technicians, allowing them to focus on interpreting results and making critical decisions.

Next-Generation Sequencing (NGS): Transforming In-Vitro Diagnostics

NGS stands as a revolutionary force, reshaping the landscape of human diagnostics. With its ability to decode the intricate genetic makeup of individuals with unprecedented precision, NGS has added immense value to IVD, aligning seamlessly with recent trends in personalized medicine and precision diagnostics.

NGS, also known as high-throughput sequencing, has unleashed a genomic revolution. Traditional diagnostic methods often provided limited insights into genetic disorders, requiring multiple tests and often leading to diagnostic odysseys for patients. Enter NGS, which enables the simultaneous analysis of thousands of genes, offering comprehensive genetic profiles. This has been pivotal in diagnosing rare genetic diseases, identifying cancer mutations, and predicting susceptibility to various conditions.

Recent trends in IVD emphasize personalized medicine, where treatments are tailored to an individual's genetic profile. NGS plays a central role in this shift, offering the ability to identify specific genetic mutations that guide treatment decisions. For example, in oncology, NGS allows for the selection of targeted therapies based on the genetic alterations driving a patient's cancer. This precision minimizes side effects and enhances therapeutic outcomes.

Another critical trend is the emphasis on early disease detection. NGS excels in this domain by detecting trace amounts of genetic material from pathogens, facilitating rapid and accurate diagnosis of infectious diseases. In the wake of the COVID-19 pandemic, NGS was instrumental in characterizing the virus and developing diagnostic tests.

Furthermore, NGS contributes to the advancement of non-invasive prenatal testing (NIPT), enabling the detection of fetal genetic abnormalities from a simple maternal blood sample. This minimizes the risks associated with invasive procedures like amniocentesis.

NGS has not only added value to human diagnostics but has become its cornerstone. Its capacity to unravel the intricacies of the human genome aligns perfectly with current IVD trends towards personalized medicine, early disease detection, and non-invasive testing.

NGS and MS: A Powerful Synergy in Modern Diagnostics

NGS and MS are cutting-edge techniques, while distinct in their applications, are increasingly becoming intertwined, creating a synergy that's revolutionizing human diagnostics.

NGS, the herald of the genomics era, has shattered the boundaries of what's possible in diagnostics. It offers an unprecedented ability to sequence entire genomes, enabling clinicians to identify genetic variations, mutations, and novel biomarkers with astonishing speed and precision.

On the other side, MS reigns supreme in molecular analysis. Its precision in identifying and quantifying molecules is unparalleled. MS can detect and quantify proteins, metabolites, and even small molecules?

What's truly exciting is how NGS and MS are joining forces in the diagnostic laboratory. NGS provides the genetic blueprint, identifying potential genetic mutations and variations that could be linked to disease. MS, in turn, delves into the functional aspects, quantifying proteins, metabolites, and other molecules, highlighting the actual impact of those genetic variations.

This integration has profound implications. For example, in cancer diagnostics, NGS can identify gene mutations associated with tumour formation. MS can then detect specific proteins or metabolites related to these mutations, providing clinicians with a more comprehensive understanding of the disease's progression and potential therapeutic targets.

Conclusion

In the not-so-distant future, we can expect NGS and MS to work hand-in-hand routinely in diagnostic laboratories, unlocking new frontiers in healthcare. As these technologies continue to evolve, we can anticipate even greater precision, faster turnaround times, and more personalized treatments.

The convergence of NGS and MS represents a thrilling chapter in the story of diagnostics. Together, they offer a holistic view of diseases, from their genetic origins to their molecular manifestations. This dynamic duo promises to reshape the diagnostic landscape, enabling us to deliver more precise, effective, and personalized healthcare to individuals around the world. The future of diagnostics has never been more promising!.

Changes in the Energy Sector: Implications for Analysis Instrumentation

Gautam Rajan
Managing Director
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Mumbai

The world is facing a pressing need to transition from fossil fuels to more sustainable and environmentally friendly energy sources. Biofuels, Green hydrogen, and Sustainable Aviation Fuels (SAF) represent promising alternatives that can significantly reduce carbon emissions across various sectors, including transportation and energy production. Global investments into clean energy have been on the rise now for several years

As per the Ministry of Petroleum and Natural Gas (MoP&NG), India is the world's third largest energy consuming nation and a significant part of India's energy requirement is met through fossil fuels, specially oil, which continues to rely largely on imports. India's share in global energy consumption is set to double by 2050. A rising energy demand and high reliance on import poses significant energy security challenges. It also leads to massive foreign currency outflow. Further, excessive use of fossil fuels leads to higher carbon emissions and associated health concerns. Historically the reliance on fossil fuels has been based on their ease of availability, abundance in nature, energy security requirements and the existence of technology to convert them into useful energy. Thus the transition to cleaner energy is a challenge, especially for emerging economies as is evidenced by unabated investments in fossil fuels specially in India, China and Africa. However, increasing incidences of extreme climate change events, greater public health awareness and visible detrimental effects of residual components of fossil fuel use on our natural resources are driving the search for newer and cleaner energy sources.

While nuclear, wind and solar energy have been the focus of such search, there is a far greater amount of resources being directed now towards an immediate and urgent reduction in the use of fossil fuels. This urgency manifests in multiple policy directives by governments

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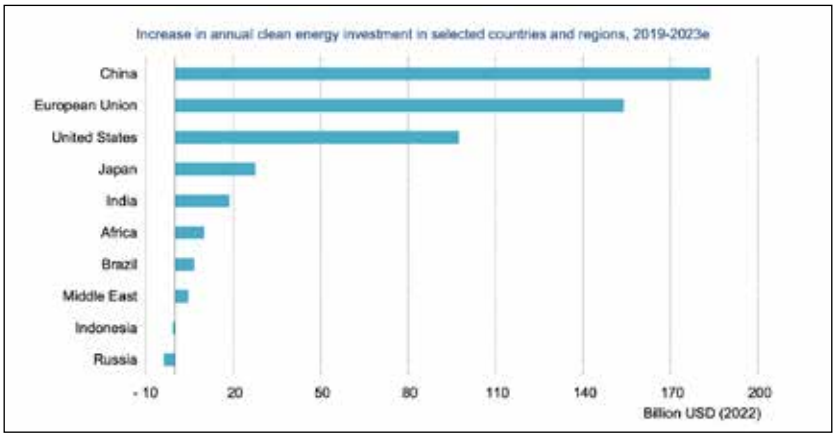
and agencies across the globe in the following areas and India is no exception:

- Ethanol Blended Gasoline
- Biodiesel
- Synthetic Aviation Fuel
- Green Hydrogen

These represent promising alternatives that can significantly reduce carbon emissions across various sectors, including transportation and energy production.

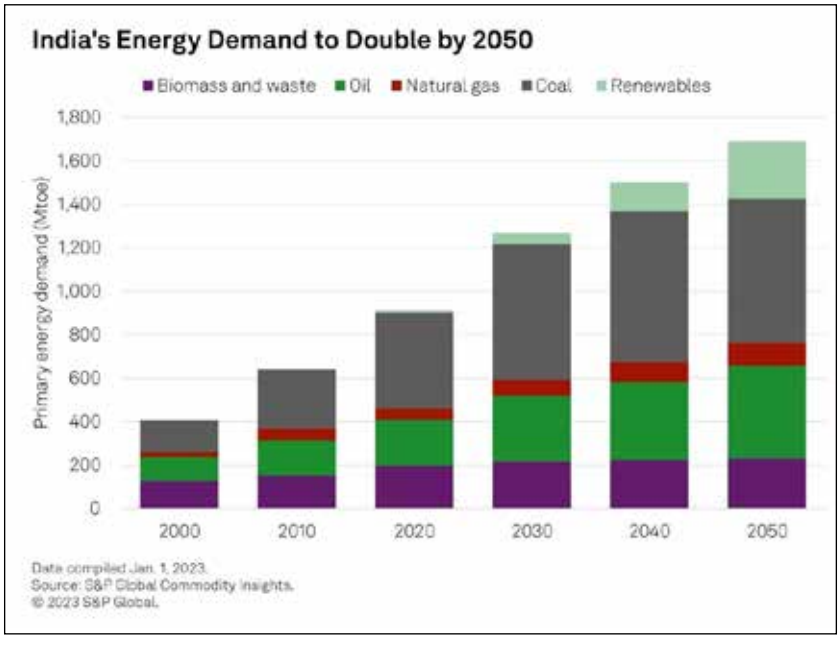
India's current and future energy needs are very well reflected below. While demand for energy is ever increasing reflecting economic growth, it is clear that investments in nextgen energy are likely to increase exponentially.



Technological Advancements

The drive towards these nextgen fuels is being propelled by multiple technological advances

- **Advanced Biofuel Production:** The development of advanced biofuels, such as cellulosic ethanol and algae-based fuels, is gaining momentum. These fuels offer higher energy yields and lower emissions compared to traditional biofuels.
- **Waste-to-Fuel Conversion:** Innovations in waste-to-energy processes are enabling the conversion of agricultural, domestic and municipal waste into biofuels, reducing waste and greenhouse gas emissions.
- **Synthetic Biology:** Advances in synthetic biology are enhancing the efficiency of biofuel production by engineering microorganisms for more effective bioconversion.
- **Electrolysis:** Advances in electrolysis technologies are making green hydrogen production more cost-effective and efficient, with a particular focus on proton-exchange membrane (PEM) and alkaline electrolysis.
- **Renewable Energy Integration:** Integration with renewable energy sources, such as wind and solar, is crucial for the development of green hydrogen. Power-to-Gas (P2G) projects are gaining traction.
- **Advancements in processes** like Fischer-Tropsch synthesis, Hydroprocessed Esters and Fatty Acids (HEFA) and Alcohol-to-Jet (ATJ) are enhancing the efficiency of SAF production from a variety of feedstocks. Drop-in SAF that can be used without modifying existing aircraft engines is also a focus of significant research and development.



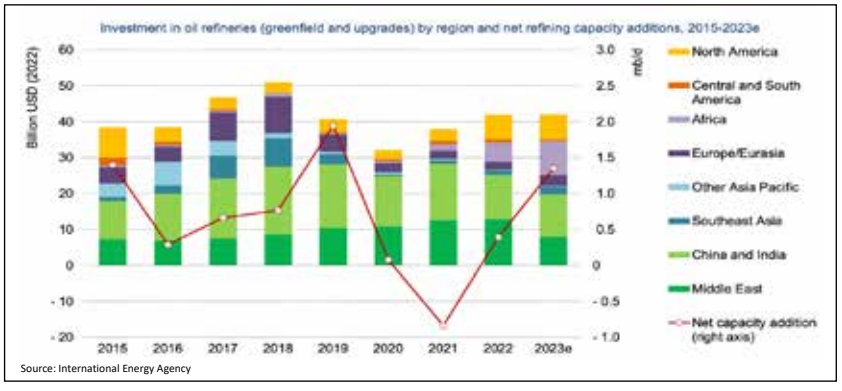
> ***India is the world's third largest energy consuming nation depending on fossil fuels. With India's share in global consumption set to double by 2050, there has been a major focus in shifting to alternate sources – Ethanol blended gasoline, biodiesel, synthetic aviation fuels, green hydrogen etc.***

Policy Drivers

The Ministry of Petroleum & Natural Gas (MoP&NG) has already mandated the oil companies to sell Ethanol Blended Petrol (EBP) with percentage of ethanol up to twenty per cent throughout the country from April 1, 2023. Blending of ethanol in petrol will gradually be increased in the coming years. A target of 20% blending of ethanol in petrol is proposed by 2025-26. An indicative target of 5% blending of biodiesel in diesel / direct sale of biodiesel is proposed by 2030. This goal is to be achieved by:

- reinforcing ongoing ethanol / biodiesel supplies through increasing domestic production (b) setting up Second Generation (2G) bio refineries
- development of new feedstock for biofuels
- development of new technologies for conversion to biofuels
- creating suitable environment for biofuels and its integration with the main fuels.

India also plans to mandate the use of 1% of sustainable aviation fuel (SAF) for domestic airlines by 2025, in a bid to cut emissions from the sector. Unlike the United States and the European Union, India does not have policies governing sustainable aviation fuel yet. The European Commission SAF mandate is expected to start in 2025 with a minimum volume of SAF at 2%. This will drive the aviation sector in India also to meet or exceed this requirement.



Source: International Energy Agency

By far the most prominent amongst government initiatives is the National Green Hydrogen Mission. One of the mission outcomes projected by 2030 is the development of green hydrogen production capacity of at least 5 MMT (Million Metric Tonne) per annum with an associated renewable energy capacity addition of about 125 GW in the country.

Carbon pricing mechanisms and carbon markets are incentivizing the use of low-carbon biofuels by assigning a value to carbon emissions. Similarly, tax credits and incentives for biofuel production and consumption are encouraging investment in the biofuels sector.

Implications For Analysis Instrumentation

As we transition from fossil fuels to the next gen fuels, there is a paradigm shift to be expected in analysis requirements.

Research & Development

With the emphasis on the usage of multiple feedstocks for development of biofuels, there will be a huge requirement for advanced instrumentation to meet the analysis needs for raw material analysis, process development monitoring, conversion efficiency of the process, energy efficiency and carbon footprint of the finished products. The government has incentivised companies and institutions for undertaking R&D and setting up demonstration projects and specialized centers in high technology areas. Some key identified areas of intensive R&D work include

- Biofuel feedstock production
- Advanced conversion technologies from identified feedstock

- Technologies for end use applications including modifications for biofuels
- Utilization of bi-products of biofuels.

Quality Standards

The government has mandated the Bureau of Indian Standards to work on the development of test methods, procedures and protocols for different biofuels and end use applications. The Bureau of Indian Standards (BIS) has already evolved standards for bioethanol, biodiesel for standalone and blended form applications. Development of specifications for higher blending levels are underway. The Bureau of Indian Standards (BIS) would review and update the existing standards, as well as develop new standards for devices and systems for various end use applications.

Future Trends

- The key change will be the transition from measure desirable components in a fuel mix to the detection and analysis of undesired components (contaminants) in single composition fuels like 100% biofuels or green hydrogen
- Spectroscopic techniques, combined with advances in chemometrics and AI, will drive the innovation in the next generation of instruments
- As environmental consciousness percolates to a consumer level, low-cost, portable and small instruments that provide real-time monitoring of emissions and pollutants from consumer goods like cars or air-conditioners will increase. These could be capable of detecting and quantifying various harmful compounds, such as sulphur, nitrogen oxides, and particulate matter.
- Integration with Control Systems: Instruments will need to integrate seamlessly with control systems to enable automatic adjustments and optimizations to meet emissions standards.
- Remote Monitoring: Remote monitoring capabilities will be essential to ensure compliance across multiple facilities.
- Machine Learning and AI: Machine learning algorithms will play a significant role in data interpretation and predictive maintenance, helping operators make informed decisions.

In the present, analysis instruments are evolving to meet the demands of an increasingly complex and environmentally conscious industrial landscape. Stricter regulations, technological advancements, sustainability concerns, energy efficiency goals, and market expansion are driving the development of more advanced and capable instruments.

As we look to the future, our industry must prioritize innovation, collaboration, and adaptability to continue to play a vital role in enhancing efficiency, reducing emissions, and supporting sustainable industrial practices. Meeting these requirements and staying ahead of emerging trends will be essential for both, us and the industries we serve. Needless to say, earth and humanity will also benefit from this evolution!

Sources

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2. *Websites of MoP&NG, Ministry of New and Renewable Energy, IREDA and Niti Aayog*
3. *International Energy Agency*
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Revolutionizing Analytical Testing in India: Harnessing Cutting-edge Technologies to Expand Horizons

Amit Chopra
Managing Director
India & South Asia
Thermo Fisher Scientific
Mumbai

India is poised to become a key market in the global landscape of analytical instruments, as the industry is expected to undergo substantial growth. This growth is primarily driven by the government's investments in research and development and an increased demand for bioanalytical testing in the pharmaceutical and biopharmaceutical industries. In contributing to India's scientific progress, Thermo Fisher Scientific, the world leader in service science, offers a comprehensive portfolio of cutting-edge technologies. These include advanced instruments for drug development and proteomics research, as well as innovative methods and workflows for ensuring food safety. Furthermore, Thermo Fisher Scientific displays its commitment to environmental sustainability by developing analytical solutions for monitoring air and water quality, as well as evaluating electric vehicle batteries.

In an era driven by an unwavering commitment to sustainability and innovation, analytical instruments have become indispensable catalysts, propelling progress and transformation across diverse industries. From life sciences to the critical domains of healthcare, food, forensics, and clinical research, these precision instruments are pivotal drivers, advancing research and discovery and ensuring uncompromised quality control standards.

The global landscape of analytical instruments is poised for a remarkable growth trajectory with a projected CAGR of 6% from 2023 to 2028. Notably, India is emerging as a significant market and is slated to grow at an impressive CAGR of 11% over the next eight years. This unprecedented growth is propelled by substantial government investments in R&D, coupled with the rapid expansion of the pharma and biotech sectors, thereby fueling innovations.

Additionally, strategic collaborations, technological advancements, regulatory compliance, and market demand are driving growth and development.

Meeting the needs for localization in India

The government's 'Make in India' initiative has greatly boosted investments, leading to setting up of world-class infrastructure and streamlining procurement processes, to position India as a manufacturing, design and innovation hub.

Thermo Fisher is actively contributing to India's scientific and technological progress through our commitment to growth and breakthrough innovations. As an effort in this direction, we are going to locally manufacture air quality monitoring analyzers at our manufacturing hub in Nashik, Maharashtra, aligning with India's ambitious sustainability and 'Make in India' goals. Moreover, the Nashik plant serves as a hub for the manufacturing and assembly of instruments for trace chemical analysis and liquid handling.

These analyzers are utilized for wide-ranging applications in diverse sectors including pharmaceutical manufacturing, oil and gas, mining, iron and steel, cement, power generation, and other industries, serving state and government entities.

Fostering innovations in the life sciences industry

Technological innovations within laboratory analytical equipment,

such as chromatography, mass spectrometry, and thermal analysis, have the potential to revolutionize the life sciences industry.

Thermo Fisher Scientific offers a comprehensive portfolio of cutting-edge technologies that support the entire drug development workflow from fundamental research to commercialization. These advanced instruments enable precise analysis, allowing researchers to assess pharmacokinetics, identify impurities, and confirm the chemical composition of drug formulations.

In the field of genomics and proteomics, Thermo Fisher is accelerating research through breakthrough technologies that enhance our understanding of biology and expedite the development of novel therapies and treatments. For example, the recently launched Thermo Fisher Orbitrap Astral mass spectrometer combines fast throughput, high sensitivity, and deep proteome coverage to allow researchers to uncover proteins, identify new clinical biomarkers, detect diseases earlier and develop new targeted therapies for various conditions, including cardiovascular diseases and cancer.

Orbitrap Astral represents one of the most significant advancements in mass spectrometry in the last 15 years. It builds upon Thermo Fisher's proven Orbitrap mass spectrometry platform, delivering up to 2x deeper proteome coverage and up to 4x times more throughput compared to existing mass spectrometers.

Moreover, the Krios cryo-electron microscope provides unprecedented insights into protein and virus structures, accelerating the development of better cures. Systems like the Vanquish Duo UHPLC increase sample throughput while reducing cost per sample, bringing about a revolution in analytical efficiency. These advanced solutions have played a crucial role in understanding the structure of the SARS-CoV-2 spike protein and have contributed to the development of effective vaccines.

In clinical settings, analytical instruments aid in diagnosing diseases, monitoring patient health, and conducting critical laboratory tests, providing accurate and timely results for making informed medical decisions.

Enhancing food safety and quality

Ensuring the integrity of food is crucial for a healthy population and economy. In a country where the burden of food-borne illnesses is comparable to malaria, HIV and TB, food safety is a priority. Each year India reports approximately 100 million cases, a number projected to increase by 50% by 2030. To combat this, effective food testing measures are necessary at every step of the value chain, including agriculture, processing, packaging, labeling and delivery.

The Food Safety and Standards Authority of India (FSSAI) has deployed various strategies to enhance crop productivity, minimize pesticide usage, curtail emissions during food processing and conduct rigorous food testing and quality checks, throughout packaging, labeling and delivery.

In line with these efforts, Thermo Fisher Scientific collaborates closely with customers to develop innovative methods and workflows that facilitate the analysis of various contaminants, additives, sugars, minerals, vitamins, veterinary drugs, and other organic contaminants.

Thermo Fisher's advanced mass spectrometry and chromatography workflows enable highly sensitive screening of contaminants, both known and unknown, even at low

Amit joined Thermo Fisher Scientific India in May 2007 as Managing Director for their Laboratory Products Group in India, and was named Managing Director for Thermo Fisher's India and South Asia operations in March 2011.

Amit started his career at ICI in India where he served for 18 years in a variety of commercial, M&A, manufacturing and General Management roles based in India as well as in Kuala Lumpur, Malaysia, where he managed commercial and operations functions for ICI's specialty chemicals business, Uniqema, for Asia Pacific.

Amit holds a bachelor's degree in Chemistry from St. Stephen's College, Delhi University, an MBA from XLRI India, and an Advanced Management certificate from Leeds University Business School, UK.

Amit was recognized as one of "India's Best Leaders in Times of Crisis - Large Organizations - 2021 from Great Place to Work" and 'Asia's Most Promising Business leaders by Economic Times for 2021-22 and 22-23".

levels. These workflows encompass a wide spectrum of applications, including allergen screening, shelf-life monitoring, authentication of ingredients and identification of foodborne pathogens.

For example, in the case of milk and milk products, which are often adulterated with pesticide residues, veterinary medicines, aflatoxin M1, vegetable oil, or other animal fats, a combined LC-MS/MS analysis effectively detects these contaminants simultaneously, addressing challenges of turn-around time and analysis cost. Additionally, the accurate and reliable results provided by Ion ratio mass spectrometers are valuable for detecting honey adulterations.

Thermo Fisher's cutting-edge chromatography solutions and sample preparation tools are designed to extract pesticides and organic compounds from food samples using minimal solvents and with high precision. Our NGS platform in particular, is one of the leading testing methods for identifying food fraud, especially in herbs and spices.

Safeguarding food integrity requires a collective effort. In collaboration with FSSAI, Thermo Fisher has established the Food Safety Solution Centre (Customer Solution Centre) in National Food Laboratory campus, Ghaziabad. This state-of-the-art facility is equipped with advanced analytical solutions such as Liquid and Gas Chromatography Mass Spectrometers (LC-MS/MS, GC-MS/MS), Inductively Coupled Plasma Mass Spectrometers (ICP-MS) and Next-Gen Sequencers (NGS). These instruments empower Food Business Operators (FBOs) and manufacturers to detect food fraud and adulteration effectively.

Contributing to Environmental

> ***The global landscape of analytical instruments is projected to have CAGR of 6% from 2023 to 2028.***
>
> ***Notably, India is slated to grow at an impressive CAGR of 11% over the next eight years.***
>
> ***The market for pharmaceutical analytical testing is projected to grow from USD 8.3 Bn in 2023 to USD 12.4 Bn by 2028, at a CAGR of 8.4% during the forecast period.***

Sustainability through analytical testing

Accurate and precise analytical testing is integral to fostering a cleaner and more sustainable environment. Monitoring and analysis of air and water quality are critical for the detection and identification of pollutants and contaminants. Government bodies and industries heavily rely on real-time data and insights to support their research efforts in developing renewable energy sources, enforcing regulations, and implementing effective pollution control measures.

At Thermo Fisher Scientific, we are committed to environmental sustainability as demonstrated by our company-wide sustainability program. We adhere to sustainability principles in the development of products and processes- from the design stage to the end-of-life. To align our strategy with our commitment, we have adopted multiple initiatives in India.

Our pioneering solutions, such as the Dilution Flue Gas Desulphurization Continuous Emission Monitoring Systems (FGD CEMS) and SOLA-II systems, are at the forefront of our efforts. These advanced instruments have been designed to monitor the levels of SO_2 emissions from thermal power plants, facilitating refineries in achieving their emission reduction targets. In fact, our monitoring systems are currently being utilized in the world's first 3G refinery-based ethanol project initiated by India, showcasing their effectiveness in reducing the impact of harmful gases.

Moreover, our wide range of analytical instrumentation plays a crucial role in evaluating electric vehicle (EV) batteries and their components, which is essential for the seamless transition to clean energy. Our cutting-edge mass spectrometers provide real-time, accurate analysis to monitor the purity of green hydrogen, which presents a significant economic opportunity for India and is a key focus of the government's National Hydrogen Mission.

As an industry leader in Ion Chromatography, our systems are extensively used for routine testing in water samples, evaluating toxicity, and determining organic and inorganic ion species.

Future outlook

Analytical instruments are critical for scientific exploration, quality assurance, and innovative breakthroughs in pharmaceutical and biopharmaceutical industries.

The market for pharmaceutical analytical testing is projected to grow from USD 8.3 Billion in 2023 to USD 12.4 Billion by 2028, at a CAGR of 8.4% during the forecast period.

The COVID-19 pandemic has accelerated the development of biosimilars, combination molecules, and other novel vaccines and medicines, resulting in a heightened demand for comprehensive bioanalytical testing. Additionally, the rising number of drug approvals and clinical trials worldwide are expected to drive the growth of the global biopharmaceutical analytical testing market.

According to the FDA drug recall statistics, approximately 1,279 drugs are recalled globally every year[4]. This highlights the need for testing products for impurities to ensure public safety before they are commercialized. Analytical testing plays an important role in guaranteeing the safety and efficacy of the drugs. Furthermore, an increase in R&D activities, collaborations, and strategic partnerships is expected to fuel market growth.

The Evolution of the CRO Industry in India

Dr. Tausif Monif
CEO - CEBIS

During the late 1990s and early 2000s, Clinical Research Organizations took root in India. Indian pharmaceutical companies were becoming well established in generic drug manufacturing, making clinical contract research and development services a natural progression.

Pharma manufacturers in India began exploring markets outside of the country and were among the first to launch products in advanced markets. As part of the regulatory filing process (ANDA), it was necessary to conduct bioequivalence and bioavailability studies. As most CROs conducting these studies were in North America and Europe, the cost of doing these studies was prohibitive.

It led the big generic players in India to establish sites in the country that met world standards, with one of the first sites being set up in New Delhi and being the first to undergo FDA inspections for one of the studies conducted there. This set the pace for the development and growth of multiple CROs in the country.

The Contract Research Organization (CRO) industry in India has experienced remarkable growth and evolution in recent decades. As pharmaceutical and biotechnology companies continue to expand their research and development activities, there has been a significant rise in the demand for outsourcing various aspects of drug discovery and clinical trials. India, with its cost-effective solutions, conducive regulatory environment and abundant pool of skilled professionals has emerged as a prominent player in the global CRO market.

> ***India, with its cost-effective solutions, conducive regulatory environment and abundant pool of skilled professionals has emerged as a prominent player in the global CRO market. As of today, there are over 75 CROs in India that provide preclinical/clinical, and pharmacovigilance services to the pharmaceutical industry.***

During the initial years, the Indian CRO industry mainly served domestic pharmaceutical businesses. Compared to what we see today, this business was tiny.

As a part of the Indian clinical research space since 1993, where we started the first studies to meet international regulatory requirements, the Indian CRO industry has grown significantly since the early 2000s. As of today, there are over 75 CROs in India that provide preclinical/clinical, and pharmacovigilance services to the pharmaceutical industry.

India's infrastructure, talent pool, and understanding of international regulatory requirements have contributed to this unprecedented growth. Further, India's cost advantage contributed to international generic companies conducting clinical regulatory studies in the country.

Due to a significant price differential, which is estimated to be 50-75% lower than prices in North America and Europe, both Indian and global generic players have made a strategic move to shift a substantial portion of their clinical work to India. This decision has proven to be highly advantageous, as it has provided these players with immense cost benefits.

There are several factors that make India an ideal clinical trial site such as large number of healthy subjects, the high prevalence of diseases, the treatment naïve patients, the large genetic diversity of the population, investment into Research and Development, laboratories, bioanalytical labs with some of the most advanced instrumentation and automation, some of the best hospitals in the world, and the ability to communicate in English, all of which contribute to its appeal.

The advent of digital technology and access to IT expertise in India has enabled clinical trials to be conducted more efficiently. Various aspects of drug discovery and clinical trials are in the process of incorporating Artificial Intelligence (AI), which will improve efficiency and reduce overall costs.

When it comes to running clinical trials, India has a distinct advantage. There is a highly trained workforce, and many professionals have advanced degrees in life sciences, medicine, and biotechnology. Several Indian academic institutions and research centres are contributing to the growth of the Indian CRO industry.

The Indian CRO sector continues to develop its capabilities in early and late stages of clinical research, as well as in large molecule analytical

Dr. Tausif is a highly accomplished professional with more than 30 years of experience in the pharmaceutical industry. He has a Ph.D. degree in Pharmaceutical Sciences from the prestigious Birla Institute of Technology. Throughout his career, Dr. Tausif has held various senior executive positions where he has provided strategic advice and demonstrated exceptional leadership in clinical research. As a senior executive, Dr. Tausif is known for his extensive experience in clinical research and his ability to provide valuable insights and guidance. He possesses a dynamic and analytical mindset, which enables him to navigate complex challenges and make informed decisions. Dr. Tausif is also recognized for his collaborative approach, working effectively with diverse teams to achieve common goals. As part of his responsibilities, he advised and contributed to key strategic business decisions, supported the development of key innovative products, and provided clinical and biopharmaceutical support for multiple ANDA/NDA, 505(b)2 and FTF filings. Extensive experience leading full-service CROs worldwide, Dr. Tausif is known for driving innovation and providing comprehensive clinical research solutions to the CRO and pharmaceutical industries, as well as for generating new business prospects across India, North America, Europe and Southeast Asia. Throughout his career, he has been responsible for managing large budgets, monitoring financial performance, M&A, strategic business planning, and effectively managing capex budgets and revenue expenses both onshore and offshore. His work experience includes expanding functional operations in North America, Europe, and India. As a leader, Dr Tausif possesses excellent negotiation, liaison, and communication skills. In fast-paced, target-driven environments, he has established positive relationships with clients, colleagues, senior corporate leadership, and other professionals. His efforts to improve efficiency by strengthening and developing internal systems have been well recognized. Dr Tausif is presently working as a CEO for Cebis, CEBIS, is a full-service CRO headquartered in Houston, Texas, will providing comprehensive integrated solutions for clinical research (including start-up to CSR, phase I to IV), pre-clinical testing, drug safety services, biostatistics, clinical trial supplies, and software solutions such as IRT/EDC, at highly competitive advantages and with a focus on patients' needs.

capabilities. CROs in India are growing rapidly due to the technical capabilities and infrastructure available. In the Indian CRO space, key players will be cost-effective providers of health care solutions to the international pharmaceutical industry in early and late phase clinical trials, contributing to the provision of health care solutions and passing on cost savings to patients. There is no doubt that India will continue to climb the ladder to become a global leader in the CRO sector.

The Indian CRO industry is further expanding to support several areas in the pharmaceutical R&D drug development process, among which are rare diseases, genomics, pharmacovigilance, and IT solutions in the drug development field. The CROs are also investing in preclinical research and *in-vitro* model development to comply with the new regulatory guidelines.

As the late-phase business sector has tremendous potential, building capabilities in Indian CROs will facilitate innovative research worldwide. India as stated before is an ideal site for clinical trials due to its high disease prevalence, treatment naive population, and genetic diversity.

Based on the nature and stage of the trial, the clinical trial market can be divided into different phases (Phase I-IV). Phase I clinical studies are being conducted in an increasing number in order to support the growing demand for new treatments. Many of these studies can be conducted in India. However, business opportunities are in conducting phase III clinical trials, which typically generate revenue based on large patient populations and long trial durations.

By forming strategic partnerships with global CROs, the Indian CRO industry will expand its business beyond generics. An organization's performance in late phase trials depends on the presence of a comprehensive operations team, which includes project managers, physicians, start-up teams, clinical research associates (CRAs), statisticians, data managers, and medical monitors. With the wealth of talent available in India, this is an advantage available and should be used in the benefit of creating world class teams in executing trials with a patient centric approach enabling better recruitment and retention of patients. Through these partnerships, India will provide global access to its resources and expertise, enabling collaboration, knowledge exchange, and business growth.

The India's regulatory environment has been conducive to the growth of the CRO industry. The government has implemented policies and regulations that promote clinical research and provide a framework for ethical practices. Regulatory bodies such as the Central Drugs Standard Control Organization (CDSCO) and the Indian Council of Medical Research (ICMR) have been instrumental in ensuring compliance with international standards and guidelines.

With its capability and intent to maintain global quality standards, compliance to GCP, following strong quality management systems, having EDC implemented in its processes, minimizing human intervention in data handling, having robust IT systems with cost efficiency, India is regarded as one of the world's leading clinical trial centers. This process brings in efficiencies and builds trust with the sponsors and the regulatory agencies.

Increasing global demand for cost-effective alternatives to biologics and patented drugs will present ample opportunities for Indian CROs. In addition to bringing new therapies to market more efficiently, it also plays and will further contribute in making treatments more cost-effective and bring new therapies to the market more efficiently.

The CRO industry in India, once in its infancy, has now matured into a crucial component of the global pharmaceutical and biotechnology sectors. In the future, the CRO industry in India is expected to continue to grow and diversify. Innovations in the healthcare sector will be driven by specialization, digital transformation, global partnerships, and a patient-centered approach. As a reliable outsourcing destination, India will further enhance its reputation through quality, data security, and regulatory compliance.

As a result of their continued evolution, CROs in India are well positioned to significantly contribute to the advancement of healthcare and pharmaceuticals globally, and their continued growth promises exciting prospects for both industry and patients.

Mass Spectrometry Market in India – Future Outlook

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Gurgaon, Haryana, India

- ***The Pharmaceuticals Industry is the major driver for mass spectrometry growth in India***
- ***Demand for mass spectrometers is driven by the stringent quality guidelines implemented by regulators***
- ***Recent high double-digit growth in the mass spectrometry market is driven by nitrosamine impurities analysis in API and Formulations***
- ***High demand (almost 50%) for mid-sensitive mass spectrometers in the Indian market to support major applications***
- ***Triple Quadruple mass spectrometers hold the highest market share in mass spectrometry segments in India***
- ***More awareness in High-resolution mass spectrometers for high end application***

The mass spectrometer is the most important segment of analytical technique used in the qualitative and quantitative analysis of the mass of particular molecules with high selectivity, specificity, and sensitivity. Mass spectrometry is considered as a detector technology that detects compounds after the chromatographic separation. Mass spectrometry applications are in different industries to support the quality and safety of products. The major applications of mass spectrometry are in pharma, food, clinical, biopharmaceuticals, chemicals, and many more. Mass spectrometry supports a wide range of applications including basic research, pharma discovery to development pipeline, method development and validation of small to large molecules, quality control of pharma API to formulations, to ensure the quality of agricultural and marine products export.

The fundamental principle of mass spectrometers is based on the conversion of molecules (neutrals) to ions. The ions are then separated based on their *mass-to-charge (m/z)* ratio before being analyzed by a detector. Three major components of a mass spectrometer are ion source, analyzer, and detector technology along with another small component (Figure 1). Samples in the form of solid, liquid, and gas, can be introduced in a mass spectrometer through a well-known separation device like Gas Chromatography and Liquid Chromatography. There are some other sample introduction methods like direct insertion probes and capillary electrophoresis etc. Once the sample is introduced, based on the polarity of compounds various ionization techniques can be applied to form ions. Post ionization, ions are separated in mass analyzers according to their *m/z* ratio. A variety of popular mass analyzers (Quadrupole, Time-of-Flight, Ion Trap, Magnetic sectors, Orbitraps etc) are commercially available to meet application requirements.

Mass Analyzers

Quadrupole

Quadrupole-based mass analyzer is a major invention in the mass spectrometry domain. It consists of two sets of parallel round rods which simultaneously change RF and DC currents for ion movement. Quadrupole can work in scanning, transmission and selective mode to control the ions for analysis.

Sensitivity and reproducibility make quadrupole gold standards technology for quantitation for small and large molecules with good linear dynamic range. It has also certain challenges in qualitative performance mainly due to resolution and full scanning in on-fly mode. Drug discovery and development, Pharma QA/QC, clinical diagnostic, food testing, chemical analysis, and biopharma are the major market segments where quadrupole are used for routine analysis.

Ion Traps

Ion traps provides high sensitivity in full scan mode making it suitable for the characterization of compounds during synthesis or in high throughput environment. It provides multistage fragmentation for better structural elucidation and an in-depth understanding of compounds. It has low sensitivity in quantitation and poor linear dynamic range limiting its application in the wider market. Ion traps can be connected with LC and GC for various applications.

It has high sensitivity in full scan mode due to high scanning. Ion traps can perform multistage product level analysis which provides an additional level of information during complex compound characterization. Due to its geometry and hardware design, it has poor quantitative sensitivity with a low linear dynamic range. It is easily coupled with Gas and Liquid chromatographic systems.

Time-of-Flight (TOF)

TOF-based mass analyzers are very popular in high-resolution mass spectrometry segments due to their mass accuracy, resolution, and speed. It separates ions of the same kinetic energy based on mass to charge ratio. TOF can be connected with various ionisations techniques like ESI, MALDI etc. TOF-based technology is commonly used in small and large-molecule applications covering a variety of segments like proteomics, metabolomics, natural products, and biologics. TOF can be combined with another mass analyzer like a quadrupole for wider application and provide selective fragmentation and better sensitivity.

Orbitrap

Orbitrap mass analyzer is an ion trap that utilizes a central rod-like electrode surrounded by a barrel-shaped outer electrode. Ions are injected into the barrel of the trap and swirl around the central electrode. Ion trapping occurs axially and *m/z* is determined using the harmonic oscillations in a combination of Fourier transform. Orbitrap is frequently used in many market segments like pharma, drug discovery, proteomics, lipidomics, and clinical due to its ion high resolving power[3].

Major Mass Spectrometry Application Areas

1. Drug Discovery and Development
2. Pharma Quality
3. Food and Beverage Testing
4. Clinical Research Organizations (CROs)
5. Clinical Diagnostic
6. Life Science Research

Market Demand

Mass spectrometry provides a high level of sensitivity and specificity for qualitative and quantitative applications over other technologies due to its wide range of scans and fragmentation options. Among all the technologies, quadrupole-based LC-MS/MS has grown more rapidly due to its wide range of applicability in many industries which includes pharma, biopharma, clinical, food, and forensic testing.

The total mass spectrometry market globally was estimated at around 7.3US$B in 2022 and this is expected to grow over 5.0% CAGR in the next 5 years approaching close to 9.4US$B by 2027 as per a recent report published by SDi[1]. SDi reported that overall mass spectrometry demands in India including all technologies will grow from US172 Mn to US230 Mn with a CAGR of 6% (Figure 2). In Figure 3, the growth of major mass spectrometry technology compiled and reported for the Indian market.

Pharmaceutical industries, CROs, and commercial testing labs are the major drivers for mass spectrometry in India. India is considered as global pharmacy supporting global demands and holds 3rd rank worldwide for pharmaceuticals production by volume and 14th by value. India has created a very strong footprint for 3,000 drug companies and 10,500 manufacturing units locally. The market size of the Indian Pharmaceuticals industry is expected to reach US$65B by 2024 and grow to US$130B by 2030 (Figure 4). India almost exports 20% of generic drugs to the global market. Ensuring quality is paramount for pharma companies to grow and sustain market share in a competitive global environment under strict regulation by many countries. As per the IBEF report, the Indian Pharmaceutical market supplies almost 50% requirements

Market	Application Area
Pharma	*Drug Discovery and Development, Impurity Analysis, CROs,*
BioPharma	*Development of biologics, Cell Media analysis, HC analysis, Heterogeneity*
Applied	*Agricultural, Contaminant residues analysis, Food Safety, Forensic*
Industrial	*Chemicals, Textiles, personal care,*
Diagnostic	*New Born screening, Steroids Pannel, Vit D, Biomarker analysis*
Public Research	*Proteomics, Metabolomics, Lipidomics, Natural Products, Biomarkers*

of global vaccines, 40% of the generic demands of the USA and 25% of the UK requirements. Indian pharmaceutical industry is known for its best-in-class generic and affordable medicines[2]. India exports 73.31% of drug formulation and biologicals which is highest in the segments of bulk drugs, vaccines, herbals, and surgical (Figure 5).

In the recent past the pharma companies that supply generic medicines in the USA market faced challenges due to the presence of Nitrosamines and NDSRI impurities and created a big fiasco to recall many established products. US FDA and US Pharmacopeia published several methods to detect various nitrosamines using various mass spectrometry techniques but predominantly LC-MS/MS was found to be most suitable to cover the analysis of various nitrosamines and later NDSRIs. Analysis of Nitrosamines in active pharmaceutical ingredients and finished products requires sensitivity, specificity and reproducible methods for the analysis of finished batches. This created a surge of LC-MS/MS and LC-HRMS in many pharma R&D and QC plant units. Many pharma testing labs acquired these high-end sophisticated instruments to support the pharmaceutical industries.

The biggest market in India is expected to maintain strong growth over the next 5 years due to expansion in pharma manufacturing and pharma export business. Post-COVID, some pre-clinical Clinical research organizations and CDMOs have expanded their capacity in India which fuels the growth of the mass spectrometry business. In the recent past, due to nitrosamines and the NDSRI outbreak, Indian pharma invested heavily in quadrupole-based technology to support the quality of products. In the last 2-3 years the growth of quadrupole-based technology was in the high double-digit (HDD) but this will not continue as strong as before due to multiple instruments availability at many pharma R&D and QC sites.

The mass spectrometry technology was not only limited to pharma and CRO but also played a key analytical tool in contaminant residue testing for various export products to ensure the safety and quality parameters as per the importing countries' guidelines. Important government authorities like the agricultural products export development authorities (APEDA), marine products export developmental authorities (MPEDA) funded and set-up various laboratories across the country to ensure the quality of marine and agricultural export products. These labs adopted and developed world-class methods to comply with the regulatory testing guidelines to support Indian exporters. Many triple quadrupoles, QTRAP® systems, and high-resolution based mass spectrometry

Anoop Kumar completed his M.Sc and Ph.D. in Analytical Chemistry from Gorakhpur and Agra University, respectively in early 2000. Anoop worked as a Research Associate in the division of Agricultural chemicals at IARI before moving to industry. Anoop joined Lab India (channel partner of AB) in 2006 as an application support specialist to support various customer-facing activities which drove the growth of LC-MS/MS business. In 2008, he moved to the USA to complete his post-doctoral fellowship at Tulane University, where he worked on developing LC-MS/MS methods related to protein adducts biomarkers that reduce cancer risk in humans and published some peer-reviewed publications of high impact. After completing post-doctoral research, Anoop returned to India in 2010 and joined the Application team of Labindia/SCIEX to lead a group to support the pharma and non-pharm business. He worked in the SCIEX Application support lab for 8 years with increasing responsibility before moving to a market development manager role for the pharma and CRO business. He is currently working as Senior Manager for Business Development and Marketing with key responsibilities to improve customer centricity and drive various growth initiatives across market verticals to support and sustain the business growth. Anoop has completed a one-year accelerated general management program from IIM Ahmedabad to understand various aspects of business management. He practices many Danaher business tools (DBS) to improve processes and business challenges. He has expertise in mass spectrometry-related business and published more than 30 peer-reviewed research papers, technical notes, and posters. He has presented at many events, workshops, and conferences.

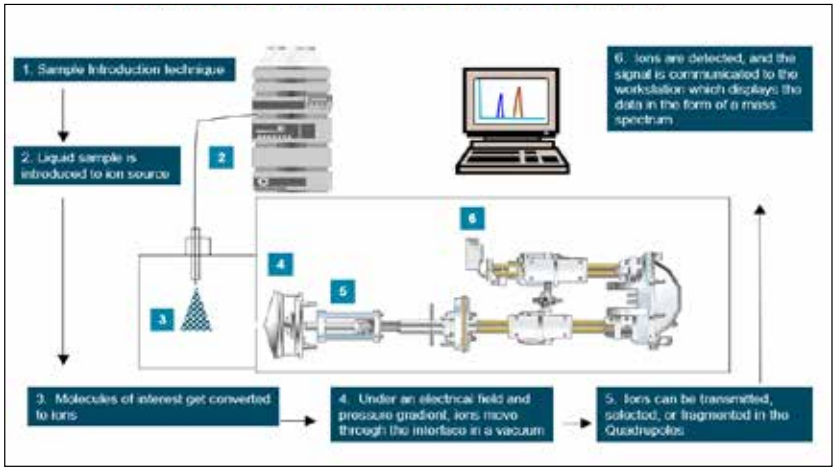

Fig. 1: General Setup of triple quadrupole mass spectrometry

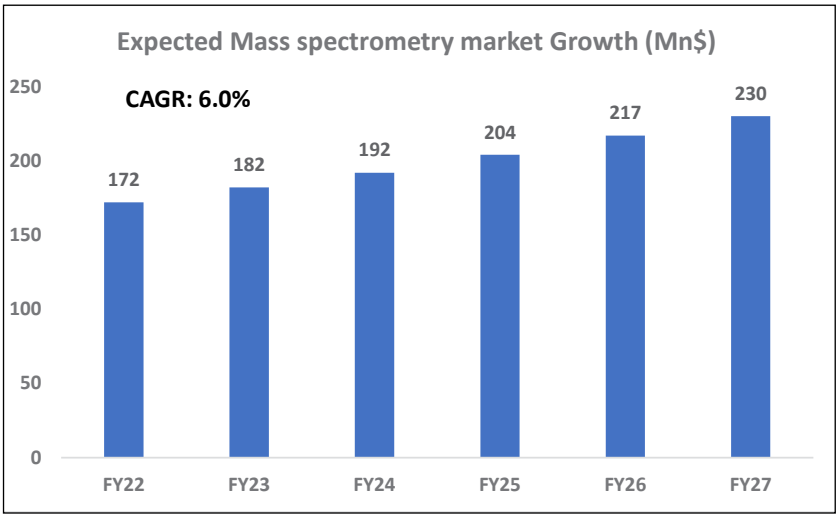

Fig. 2: Growth estimation of mass spectrometry in India for the next 5 years

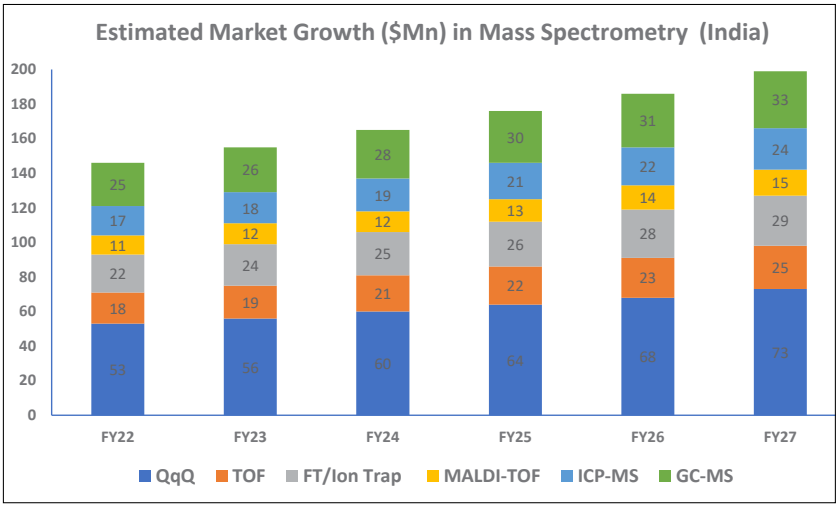

Fig. 3: Growth in major mass spectrometry technology in India

technologies are installed in many of these labs in India.

Recently Food Standards Safety Authority of India (FSSAI) which ensures the quality of food safety within the country implemented a central scheme for 'strengthening of Food Testing system in the country' started all India level project to upgrade the state food labs capability to expand the testing spectrum across many food commodities which ensures the quality of food consumed by Indian population. The scheme was to strengthen 43 state food labs across the country by supporting them with funds to procure three high-end analytical instruments, LC-MS/MS, GC-MS/MS and ICP-MS/MS along with consumable, manpower for 5-7 years. So far 39 state food safety laboratories of 29 states/UTs have been taken up for upgradation. In the last few years, these labs have produced best-class results to ensure the safety of the products that the Indian population is consuming. In the past many years, various Indian commercial testing labs (CTLs) and some global commercial testing labs have also diversified their business in India to support agricultural export product testing.

Many labs in India which were originally doing agricultural product testing have now expanded their portfolio to add impurities testing capabilities as well to sustain and grow the business. They have added various types of mass spectrometers to support the testing demands. These tests are primarily driven by the strict regulation implemented by regulatory agencies of importing countries.

Mass spectrometry technologies are also a key instrument in high-end proteomics, metabolomics and lipidomic laboratory in the country which is funded by many federal agencies like the Department of Science and Technology (DST), Department of Biotechnology (DBT) and the Council of Scientific

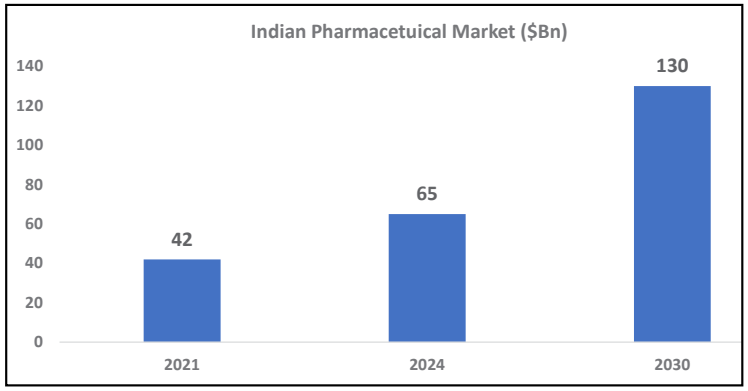

Fig. 4: Indian pharmaceuticals market

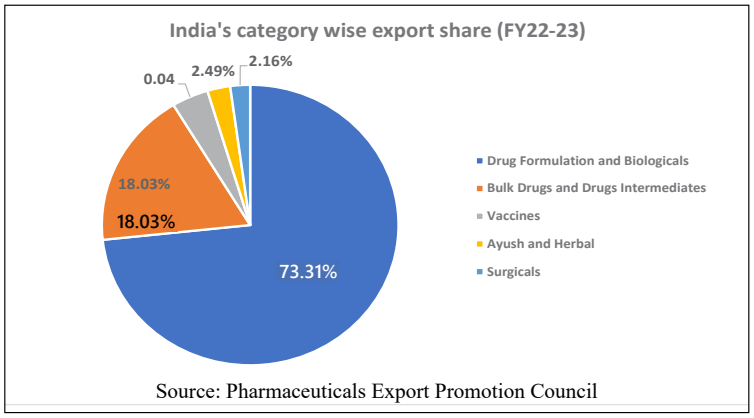

Fig. 5: Indian pharmaceuticals export segment-wise

and Industrial Research (CSIR) under various schemes. In the last decades, phenomenal growth has been observed in the adoption of these high-end instruments due to the exposure of these technologies to Indian researchers. Organizations of these mass spectrometry technologies also made great efforts to provide training and collaborate to improve the overall understanding of mass spectrometry. Even though the funding is not very consistent and the purchase cycle is long, these technologies are the still best choice when upgrading the old instruments or applying for new funds for cutting-edge research.

In the past few years, there have been major shifts observed in pharmaceutical industries where more focus is now on developing large molecules, peptides, and oligonucleotide products due to their safety and effectiveness. In various stages of development and product manufacturing, maintaining quality and safety is paramount for these biological products. Mass spectrometry plays a crucial role in determining post-transition modifications (PTMs), host cell protein impurities identification and quantification, and ensuring glycosylation consistency are the key methods developed on mass spectrometry. High-resolution accurate mass is one of the critical technologies used in biopharma characterization labs and while for quantitation of cell media analysis, triple quadruple is the choice of instruments in many biopharma labs. Even though in India, the market size of mass spectrometry is less than 5% in the biopharma industry.

Conclusion

The Indian mass spectrometry market has evolved in the past two decades in the area of application, utilization, and knowledge. The skilled manpower in this field helped immensely to adopt this technology and utilize it to produce results that help to push more products in the regulatory market. Mass Spectrometer business in India will continue to grow with mid to high single-digit and the pharmaceutical industry will be the major growth driver for the mass spectrometer business.

There is a chance that Indian pharma and food regulatory agencies mandatorily strengthen the quality and safety regulatory guidelines for testing pharma and food products for local consumption. These changes might help boost the growth of the market in upcoming years.

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HPLC Market Dynamics in India

Ravindranath Cherukuri
Managing Director
Spinco Group of Companies
Hyderabad

The Journey of Liquid Chromatography

Chromatography is a versatile method for separating and analyzing the components or solutes within complex chemical mixtures. The term *chromatography* was first documented by a botanist Mikhail Tsvet in his paper published in 1906 where he used liquid-adsorption column to separate plant pigments. Ever since this first true column chromatography came into use in the first decade of 20th century, little did anyone imagine that Liquid Chromatography would become the most dominant analytical technique today!

Liquid Chromatography is a very broad category which encompasses multiple technology segments as classified below:

- Analytical HPLC
- Prep HPLC
- LPLC
- Ion Chromatography
- Flash Chromatography
- Supercritical Fluid Chromatography
- Clinical HPLC (HbA1c).

All of the above instrumentation has seen growing usage globally and in India over the past many years. While Analytical HPLC dominates the market with a lion's share, there is increasing adoption of all other techniques listed above which I shall briefly cover in my article. However, the main focus of mine would be on Analytical HPLC as this is what drives the bulk of Indian analytical market and its growth. It is indeed my privilege to share the Indian market dynamics of HPLC with readers of this IAIA Souvenir 2023.

> - ***The Indian HPLC market, in unit numbers, witnessed CAGR of around 8% over the past years.***
> - ***The CAGR will raise around 10%, in the next five years.***
> - ***UHPLCs remain the mainstay of Front Ends to all the brands of LCMS systems and this segment is witnessing high growth rate of over 20% annually.***
> - ***Inert UHPLCs are also finding their way into the emerging market of bio pharma.***
> - ***Technology is the key driver for the future, particularly in deployment of AI, ML and Automation.***

Global Market Trends in LC Technique

The Global *Liquid Chromatography* market was valued at over US $10 Billion in 2022 and is expected to expand at a CAGR of 5% over the next 5 years. This market sizing includes sale of Initial Systems, the Aftermarket and Service revenues. Including GC and TLC, the overall Global Chromatography market is valued over US$13 Billion in 2022 with a growth CAGR of 4.8% over next 5 years.

Analytical HPLC dominates the overall sales and has a robust growth curve due to the larger adoption in high-growth pharma/bio industry, Govt./Academia as well as the emerging Applied and Industrial market segments. Pharma/Bio is bound to see significant investments in drug research, particularly *speciality drugs* which focus on prevention and treatment of various chronic diseases. The Applied sector will be propelled by rising food testing demand in Asia and the introduction of more stringent global environment regulations. Pollution control and the detection of emerging contaminants,

particularly PFAs, will fuel demand for Ion Chromatography.

The Prep HPLC market will see stronger growth due to increasing biomolecule R&D and higher throughput demands. The Clinical HPLC and SFC markets are expected to witness the highest growth over next 5 years due to increased testing of rising diabetic population driving demand for the former, while the latter will benefit from an increased focus on greener chemistry and heavy investments into sustainability measures.

Global LC Market Trends by Region

When we analyse the geographical spread of Chromatography market, the primary dominance is by USA with Europe closely following behind. The United States is the single largest end market for Chromatography as well as Analytical HPLC due to its huge pharmaceutical / biotech industry and advanced academic research facilities.

Europe contributes over a quarter of the market but the future growth is a bit subdued owing to the geo-political developments and recessionary fears. The new clinical regulations recently passed by Europe is expected to provide some fillip to clinical trials.

China rebounded post COVID with broad based growth across all end markets, especially expanding biopharma industry and increasing food and environmental testing will drive growth.

Japan has seen some stagnancy in 2022 owing to mature market conditions driving limited demand for new instruments but would witness below average market growth over forecasted five years. On the other hand, Asia Pacific countries are expected to see higher growth above average driven by increasing R&D investments and emerging as competitive pharmaceutical manufacturing hubs such as Thailand and Indonesia.

India is the bright spot contributing to over 5% of the global Analytical HPLC demand and is expected to grow at a healthy rate of 5.4% CAGR over the next five years as per market report. India has an extensive domestic API industry that heavily relies on HPLC analysis throughout the different stages of development / manufacturing and is significantly expanding production capacities to minimize dependence on Chinese imports. Analytical services segment is also

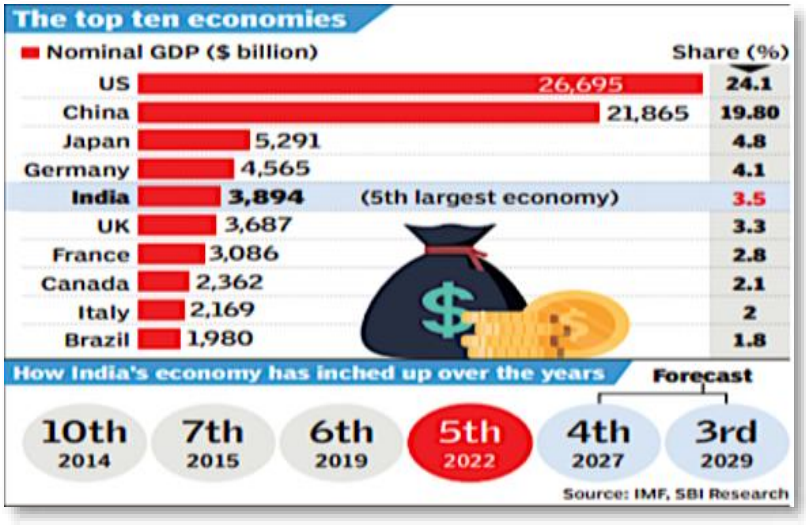
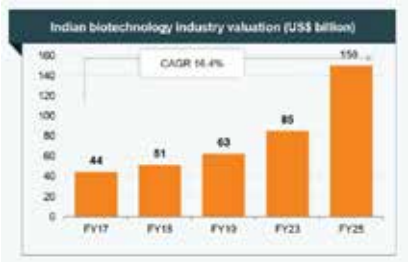


Table 1

Ravindranath Cherukuri is the Managing Director of Spinco Group of Companies and is based out of Hyderabad, India. With an experience spanning 33 Years in the Analytical Instrumentation Industry, he leads Spinco which is the largest Indian-origin BioSupplier Enterprise with a network of 55 Support Centres and 1000 Spincoites. Spinco Biotech offers end-to-end solutioning through its various Business Units of Chromatography, Mass Spectrometry, Bio Research, Process Technologies & Lab Excellence serving the Life Sciences, Healthcare, Material / Chemical and Research / Academia markets. He is on the Editorial team of CuttingEdge - a monthly technical journal published to serve the scientific community since 2011.

Source : https://www.ibef.org/industry/pharmaceutical-india

Table 2



Source : https://www.ibef.org/industry/biotechnology-india

Table 3

Source : https://www.ibef.org/industry/chemical-industry-india

Table 4

very rapidly fuelling the growth of instrumentation in India.

India Growth Story

When our Prime Minister Shri Narendra Modi announced *Amrit Kaal* Vision 2047 for India in his Independence Day speech on 15th August 2022 from the Red Fort, the whole nation woke up to realize its own potential and visualize the huge growth story in front of us. Being the 5th Largest Economy worldwide and witnessing the fastest growth amongst large economies, it is only prudent for us to say that the road ahead will be super exciting and the most memorable journey into a bright future, (Table 1).

India has many firsts to its credit - the Pharma Capital of the World, the Vaccine Capital of the World, the IT Services Capital of the World, the Largest Democracy of the World, the Youngest Demography of the World, etc. etc., and this list goes on and on. Many of these capabilities have a direct bearing on Analytical Industry as our instrumentation forms the backbone of most of the sectors such as Pharma, Biotech, Clinical Services, CRO/Testing, etc.

The origins of how India dominated the Pharma global arena go back to early 1991 when our Government opened up export markets to private players and helped build chemistry competencies through national labs and academics for starting and scaling pharma manufacturing. This Eco-system strengthened over the years with higher investments into R&D as well as Contract manufacturing.

HPLC Primary Market Segments in India

Let us deep dive into the HPLC market segments of India. Pharma is undoubtedly the largest market for HPLCs owing to its dominant use in all phases of the value-chain right from Discovery-to-Despatch. The Pharma market in India is expected to cross US $65 Billion by 2024 and grow to over US$130 Billion by 2030 (Table 2). India's pharmaceutical business is projected to grow at a healthy double-digit annual rate of ~11% over the next few years. This massive opportunity will directly drive the growth of HPLCs over this decade.

India is the 3rd largest producer of API accounting for an 8% share of the Global API Industry with about 500+ different APIs being manufactured. The largest number of FDA-approved plants outside the US are in India. We are also the world's largest supplier of generic medications, accounting for 20% of the worldwide supply by volume and supplying about 60% of the global vaccination demand.

From the traditional small molecule strengths of India, now there is significant focus into large molecules which constitute the Biopharma segment. From Biosimilars to mAbs, there is buzzing activity everywhere to build our strong presence into this upcoming high growth segment. Peptides, Proteins and Oligos are the talk-of-the-town mushrooming into huge number of start-ups as well as scale-ups across entire industry spectrum.

India's Biotechnology industry comprising of biopharmaceuticals, bio-services, bio-agriculture, bio-industry and bioinformatics has crossed US$ 80+ billion by 2022 and is expected to reach US$ 150 billion by 2025 with further potential of US$ 270-300 billion by 2030 Table 3. The Biotechnology sector, mainly due to its multidisciplinary approach, holds the potential to provide an array of solutions for challenges in various sectors such as health, agriculture, environment, energy and industrial processes.

Biologics is a major thrust area which helped us to become the Vaccine Capital of the world, growing at a high CAGR of 22% to reach US$ 12 billion by 2025. Innovative research from scratch to final product got accelerated during the COVID catastrophe by building synergistic networking between Government Research Agencies

and Private companies leveraging the PPP (Public-Private-Partnership) framework. Covaxin which is India's first indigenous vaccine showcased our capabilities to the whole world. All of the above Pharma/Bio markets will continue to be a strong enabler for HPLC market demand in India.

HPLC Applied Markets Driving Growth

There is increasing adoption of HPLCs into Applied markets in India which comprise of Chemical, Food, Agri, Herbals, Environmental, Testing, etc., apart from Government research and Academia. With the China+1 strategy, India is significantly investing into multi-fold expansion of production capacities in entire Chemical sector, be it Agrochemicals, Speciality chemicals, Intermediates, Personal care, etc., with projected market size reaching over US$ 383 billion by 2030, (Table 4).

With the largest population in the world, food production and consumption is rapidly growing which in turn drives HPLC growth. Traditional systems of medicine such as AYUSH and the natural ingredients focus is giving further push to HPLC growth. Significant exports have brought the necessity of third party Testing services which again is a natural driver for HPLC expansion. Government increased spend on translational research and academia is another growth lever for HPLC.

HPLC Key Players in Indian Market

All the Global major manufacturers of HPLC are very much present in this happening market of India. While companies such as Waters, Agilent & Shimadzu have a very long presence spanning many decades, others such as Thermo entered this segment over a decade back by acquisition of Dionex. There are also players like Jasco, Perkin Elmer, Knauer, etc.,

Analytical HPLCs

The total LC market demand is dominated by Analytical HPLCs due to their significant primary usage in all the core areas of Pharma, Biotech, Discovery, Chemical, Food, Herbal, Testing services, Academia, Government, etc.

Based on the collation of various authenticated data sources such as GOI Customs Import Data as well as the global reports prepared by various manufacturers associations across all geographies such as the JAIMA-ALDA-EUROM report etc., we can fairly reach a conclusion that the overall *Annual Indian market sizing of Analytical HPLCs initial systems sales in unit numbers would be around 4,500 systems currently*. This market sizing does not include speciality systems such as Clinical HPLCs which come under HbA1c Analysers, Ion Chromatography Analysers, etc.

The Indian HPLC market in unit numbers witnessed a CAGR of around 8% over the past couple of years (excluding COVID year). *The next five years is expected to see a double-digit growth of around 10% CAGR* due to the increasing usage and diversity of applications in core and applied markets as well as rapid upscaling of MS Front-ends.

I am herewith sharing brief updates of the major HPLC brands and their presence in the Indian market below:

Waters

Waters was founded in 1958 in Framingham, Massachusetts, USA by James Logan Waters. Waters is a global leader in analytical instruments and software serving the life, materials and food science markets. Their Indian subsidiary was formed in the year 1986 and since then Waters has been a well known brand for HPLCs in India with their initial early years business driven by research/academia and their later part growth coming from industry.

Waters introduced their first HPLC model ALC 100 in the year 1967. Their most popular HPLC model Alliance was launched in the year 1996, followed by Acquity UPLC in 2004, Acquity Premier in 2021 and latest in 2023 is their Alliance iS system. The most prominent part of their HPLC journey has been their chromatography software suite of Empower CDS and lab management systems under their Informatics portfolio. When we evaluate the current Indian Analytical HPLC market share by number of initial LC systems unit sales (# autoinjector-based systems), Waters enjoys *Top #2 position*.

Shimadzu

Shimadzu was founded in the year 1875 at Kyoto, Japan by Genzo Shimadzu Sr. with the philosophy of 'Contributing to Society through Science and Technology'. Shimadzu has four focus business areas spanning Analytical & Measuring Instruments, Medical systems, Industrial Machinery & Aircraft equipment and is the longest serving analytical instrument manufacturer in the world. In Indian HPLC market, SPINCO is the exclusive distributor of Shimadzu for over 40 years since 1983.

Shimadzu's foray in India for HPLC started in 1983 with LC-3A and it was followed in 1984 by fully automated ternary gradient model LC-4A and the world's first modular LC system, LC-6A series. These two models became quite popular, followed by the best-loved workhorse Prep LC-8A and subsequently

the LC-10A analytical HPLC with fiber optics in 1991. Then came the High Throughput Integrated HPLC concept with LC-2010 in the year 2000 which quickly became the preferred choice of pharma industry. The most popular i-Series UHPLC-Ready systems were introduced in 2014 which became an instant success leading to over 10,000 installations in less than a decade. Latest launches include Ai-Series LCs, N-Series UHPLCs and Nexera XS inert systems. Shimadzu and Spinco enjoy the *Top #1 position in India* in initial LC systems unit sales (# autoinjector-based systems) with nearly one out of every two systems imported being a Shimadzu.

Agilent

Agilent Technologies was formed in 1999 as a spin-off of Hewlett-Packard company and is based out of California, USA. Their Indian subsidiary was also formed in the same year although their HPLC presence was much earlier through couple of dealers representing them. Agilent is a global leader in life sciences, diagnostics and applied chemical markets.

Agilent's HPLC journey started in 1973 by acquisition of Hupe & Busch by HP but their popular 1100 modular series came in 1995 which were supplied in India as well. Their 1200-Series LC line-up was launched in the year 2006 followed by the Infinity series in 2010. Current HPLC models include 1220 Infinity II LC, 1260 Infinity II/Prime LCs and 1290 Infinity II UHPLCs. Agilent enjoys the *Top #3 position in India* in initial LC systems unit sales (# autoinjector-based systems).

Thermo

ThermoFisher Scientific was formed in 2006 by merger of Thermo Electron and Fisher Scientific and is based out of Waltham, Massachusetts, USA. It is a world leader in serving science and is a conglomerate formed by acquisition of various industry-leading brands such as Applied Biosystems, Invitrogen, Unity Lab Services, Patheon, etc.

Thermo's journey into HPLC began with the acquisition of Dionex Corporation in 2010 by introducing their Ultimate 3000 Series HPLCs & UHPLCs. The Vanquish platform of HPLCs & UHPLCs was launched in the year 2014 with Horizon model followed by quick model changes of Flex in 2016, Duo in 2018, Core in 2020 and Neo in 2021. Dionex brought in some unique strengths to Thermo in Ion Chromatography, CAD (Charged Aerosol Detectors) and Chromeleon CDS software. Thermo has been continuously striving to penetrate the HPLC market in India and based on current data trends available, they have reached *#4 position*.

UHPLC Trend

Although the initial emphasis and expectation was high on UHPLC technology to replace regular HPLCs across all markets, the adoption trend was not so high putting to rest the initial euphoria! UHPLC systems were expected to lead in growth, driven by the pharma/bio sector and their ability to perform faster separations compared to regular HPLCs. However, higher costs and maintenance requirements limited their usage and consequently, a new trend of UHPLC-Ready systems started to emerge and flourish in the market. These systems offered the advantages of both worlds and the ease-of-use to chromatographers which catapulted this category to the most selling systems in India.

When we evaluate the standalone UHPLC segment of India, Waters has a good presence with their Acquity™ UPLC systems followed next by Shimadzu N-Series™, Agilent 1290 Infinity II™ series and Thermo Vanquish™ Flex systems.

However, UHPLCs remain the mainstay of Front-ends to all the brands of LC-MS systems and this MS Front-end segment is witnessing high growth rate of over 20%+ annually. Inert UHPLCs are also finding their way into the emerging market of Biopharma in India. The average market sizing of total UHPLC systems in India is *well below 20% of the Total Annual LC market* and this category is expected to nudge upwards by just a couple of percentage points owing to increase in MS and Biopharma consumption over next few years.

HPLC Aftermarket

The HPLC Aftermarket sales is also a significant portion which primarily comprises of Accessories, Components and Consumables sales to the entire installed base across India. By revenue measure, this total aftermarket portion contributes to more than 50-55% of the total Indian LC market revenues. LC Columns and chemistries constitute the lion's share of aftermarket followed by GC Columns, Sample Prep such as SPE, vials/septa, tubings, etc. This Aftermarket segment is dominated by players such as Waters, Sciex, Phenomenex, Agilent, Shimadzu, Thermo, GL Sciences, Daicel in chiral, etc., with very many other brands having smaller presence. This market segment is having a healthy growth rate of double digit owing to the increase in manufacturing testing, research and academia.

Future Drivers of HPLC Growth

Technology is the key driver for future of HPLC and there are significant developments seen in

this space, particularly in deployment of AI/ML and Automation. COVID has been a major driver for adoption of Automation as well as flexible lab workspaces with remote working capabilities. The Autonomous technologies which we often see in Automobile driving, Remote surgeries, Space missions, etc., are now becoming a reality into Analytical Labs. More and more labs of the future would deploy smart automated workflows optimized for QA/QC, Analytical R&D, Testing, Accelerated Method Development, etc., which significantly enhance robustness and productivity generating reliable data independent of the experience levels or expertise of users!

Another key trend which is gaining traction of late is remote operation using advanced technologies such as Digital Twinning in which seamless automation of the entire end-to-end workflow can be achieved on an integrated Eco-system right from test planning, method development, sample analysis, data acquisitions, processing of results and reporting. Robotics can automate the transfer and dispensing of samples to various types of processing equipment, greatly reducing human labour on repetitive tasks and also minimizing human intervention. Lab Analytics is gaining significance with live dashboards reflecting real-time enterprise-level tracking of actual utilization of Instruments, Analysts and Projects.

Collaborative robots are beginning to co-work with analysts in laboratories reinforcing their actions thereby increasing development efficiency and productivity. This collaborative work between humans and cobots will surely become the future trend to be seen across many analytical labs worldwide.

Eco-friendly and Energy-saving attributes are also seeing very good traction with all manufacturers focusing on sustainability and green concepts apart from becoming more compact in footprint. Latest systems being offered consume extremely low power <90% compared to earlier systems and also automatically managing sleep modes / shut-downs based on actual usage.

Conclusion

HPLC category will continue to be the mainstream growth driver amongst all Analytical instrumentation owing to its ever-expanding and versatile range of applications spanning across all the market segments including many new emerging fields. We are fortunate to be part of this very vibrant and high growth Indian market which will witness multi-dimensional significant expansion in the forthcoming *Amrit Kaal* of next 25 years by 2047 when we all celebrate not only 100 Years of Indian Independence but also becoming a Developed Nation.

Ion Chromatography

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> ***Ion chromatography (IC) has become the most dominant method in ion analysis, replacing many time-consuming and laborious wet-chemical methods such as gravimetry, nephelometry, and turbidimetry. Minimum Detection Limit is usually parts per billion (ppb), without any need for additional equipment. Apart from traditional applications in pharma, vaccines, polyscaccharides, emerging markets for IC include lithium/sodium ion batteries and bromate testing in packaged drinking water etc.***

About 50 years now post its birth and development, ion chromatography (IC) has become the most dominant method in ion analysis, replacing many time-consuming and laborious wet-chemical methods such as gravimetry, nephelometry, and turbidimetry. While IC was focused more primarily on the analysis of inorganic anions and cations, today it is possible to analyse organic ions like the organic anions, amines, amino acids, carbohydrates and transition metals in various matrices. Ion Speciation is possible. For example Cr^{+3} & Cr^{+6}; Fe^{+2} & Fe^{+3}; selenate & selenite; arsenate & arsenite, separation is possible.

Minimum Detection Limit is usually parts per billion (ppb), without any need for additional equipment. An ideal instrument for trace level analysis. Determination down to single-digit ng/L levels after pre-concentrations has become routine in the semiconductor and nuclear power industries. Per sample analysis cost is very low as compared to any other existing technique. No shelf life of any of the components.

Instrumentation

In contrast to HPLC, IC was not initially feasible with direct (conductivity) detection mode because of the high background conductivity of the eluents. Only the development of a post-column reaction - the so-called chemical suppression - made IC possible. Chemical suppression generally has a longer life and supports low running cost. The next important step was the development of high-performance conductivity detectors with highly shielded and thermostated detector blocks. They opened IC to direct and suppressed conductivity detection, thus widening the application range from strong and medium strong acid anions to the full range of anions. For cation determination, columns that separated alkali and alkaline earth metal cations ushered in a new era. Even more because ammonium and amines – not detectable by AAS and ICP – could then be easily separated and determined. High-capacity and solvent compatible columns have been developed. A stronger focus has been placed on further detection modes such as UV-VIS, amperometry and hyphenation with MS & ICP-MS.

Sample Preparation

Crystal clear, clinically pure, no bacteria and no particles - would be an ideal sample for ion chromatography. Unfortunately, things are often very different in real life. Apart from the ions to be determined, the samples still contain matrix components, which may be aggressive or lead to precipitation in the system. They can sometimes make analysis difficult, if not impossible. Samples with a high load can destroy the separating column or lead to blockages in the system. That is why suitable sample preparation is essential for reliable and accurate analysis. In the past, all sample preparation steps had to be carried out manually. This

is history. With the unique inline sample preparation techniques, it is now possible to automate these processes in full and make each individual step traceable. The high precision and accuracy are based on the outstanding properties of the liquid handling device used for the same. The advantages are obvious: you save a significant amount of time and cost, while also increasing the reliability of your analyses. The sample preparation techniques include filtration, dilution, dialysis, neutralization, pre-concentration, matrix elimination etc. With this kind of sample preparation techniques, it is possible to analyse difficult samples with high matrix effects like milk, leather extract, engine coolants, cutting oil, petroleum products etc., directly by IC.

Application Areas and Markets

In Indian market, the technique has been traditionally used in academia, water research institutes- be it government or private, pollution control where they study all kinds of water, waste water, surface water, ground water and suggest mitigation, remediation in case the samples fail; speciation studies are another biggest area of interest. This determines which ionic species is more toxic.

Pharmaceutical market is one of the biggest and very promising industry where they are interested in ionic impurities and degradation studies. In fact, IC has replaced the traditional techniques and been accepted by pharma regulatory authorities in their modernization drive. Now that the Government of India has introduced the PLI scheme, our reliability on imports comes down, this sector is poised for bigger growth in the coming years.

In biopharma, vaccine manufacturers are using IC for polysaccharides analysis. Also in protein based drugs it has been used for the determination of sugars and glycoproteins.

Energy industry like thermal and nuclear plants have been using IC as one of the techniques for monitoring the health of the boilers. Now that power demand is increasing, this segment is augmented with more nuclear and thermal plants.

Emerging markets for IC in the energy sector include lithium/sodium ion batteries, research and quality control of electrolytes, electrode materials and quality control of the baths of solar photovoltaic modules.

Food testing is slowly gaining importance in our country. IC has been recommended as one of the important techniques in FSSAI and BIS methods for the bromate testing in packaged drinking water, anions in drinking water and nitrite & nitrate in fish and fish products. We are sure that more IC methods will be incorporated in the coming years. The development and application of ion chromatography (IC) for the quantitative determination of low-order explosives-related ionic species in environmental and forensic sample types is one of the key applications.

Chemical sector-fine and speciality chemicals, chloralkali, polymers, the use of ion chromatography has been extensive, and this sector is poised for growth.

Semiconductor industry is in a nascent stage right now and with the PLI scheme, this industry is poised for growth. As this is a water

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intensive industry, need for an IC for testing impurities is imminent both for laboratory and online models.

The exploration and production of petroleum products involve numerous applications of IC in which inorganic and low-molecular weight organic ions are determined in fuels, lubrication oils, gas washing solutions, and the so-called formation water that is a by-product of crude oil drilling.

Combustion IC is the modern combination of pyrolysis and ion chromatography. With this coupling, it is possible to analyze solids, liquids and highly viscous samples and gases fully automatically. In contrast to previously employed methods (e.g., sample digestion with the oxygen bomb), no time-consuming manual steps are needed in combustion IC.

Air analysis

The old cliché that ion chromatography can only be used to analyze liquid samples is no longer valid. Modern inline sample preparation methods also allow gases and solids to be analyzed, so the way is open for new application areas. Air analysis has become more important in recent years in recognition of the adverse effects of atmospheric pollution on human health. No matter whether you want to analyze air or other gaseous samples – two possibilities for determining the ionic components in your samples are as follows.

A sample preparation module that samples aerosol particles from an airstream and transfers them to the aqueous phase. When it is combined with an ion chromatograph, it is possible to determine all water-soluble anions and cations in aerosols very easily at the same time. The advantages of this coupling technique are obvious. The ionic profile of aerosols can be analyzed with a high time resolution of only 15 minutes. Typical areas of application are monitoring of pollutants inside buildings, emission control at the workplace, monitoring of ambient air, measurements of tunnel air, determination of stack emissions, analysis of fine dust or mobile use, e.g., on aircraft / automobile / ship.

An online ion chromatograph that completely integrates sample preparation for gaseous samples is also available. The system determines the entire water-soluble ionic load of aerosols and the gas phase. Anions and cations are measured in parallel. Compared with filter packs, this system is more economical to maintain and allows a better time resolution. This system provides exact hourly results, round the clock and seven days a week; and, if required, these can also be sent to any location *via* the Internet. The data can be used to establish trends, monitor pollution, examine movements of air masses and to study the day-night rhythm. The system can be used for online monitoring of environmentally relevant parameters such as SOx, NOx and NH_4.

IC in future

Ion chromatography will be applied to a broader range of applications, both in the lab and in process analysis. The analyst's dream would be to place the sample on the autosampler, press the start button - and get the result. Sample handling will be much more automated with respect to sample preparation but also with respect to quality assurance. The software will focus more on plausibility and quality checks of results. Moreover, for multiparameter analysis, the combined and hyphenated ion analysis, such as IC and titration, IC & Voltammetry, IC & ICP-OES, IC-ICP/MS, IC-MS etc., are now witnessing demand. The hyphenated techniques are making easier to analyse difficult samples and also increasing the sensitivity.

- Market is about 125 - 150 systems with valuation of 7 million USD. The spares, accessories & consumable market is approximately 2 million USD.
- Metrohm and Thermo are the two major companies. Majority of the HPLC companies do have Conductivity, Electrochemical and UV-Vis Detector used in ion chromatography and potentially can also be supplier of ion chromatography systems.
- Growth is slow and expected to be around 10%.
- Pharmaceutical market has the lion share in terms of turnover.

Not without my Helium as Carrier Gas in GC-MS

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GC-MS is an analytical method that combines the features of gas chromatography and mass spectrometry to identify different substances within a test sample. Applications of GC-MS include drug detection, fire investigation, environmental analysis, explosives investigation, food and flavor analysis, and identification of unknown samples, including that of material samples obtained from planet Mars during probe missions as early as the 1970s. GC-MS can also be used in airport security to detect substances in luggage or on human beings. Additionally, it can identify trace elements in materials that were previously thought to have disintegrated beyond identification. It allows analysis and detection even of tiny amounts of a substance.

The first on-line coupling of gas chromatography to a mass spectrometer was reported in the late 1950s. An interest in coupling the methods had been suggested as early as December 1954. The development of affordable and miniaturized computers has helped in the simplification of the use of this instrument, as well as allowed great improvements in the amount of time it takes to analyse a sample.

The Global GC and GC-MS market is anticipated to rise 5-8% rate during the forecast period, between 2023 and 2030. In 2023, the market is growing at a steady rate and with the rising adoption of strategies by key players, the market is expected to rise over the projected horizon.

- ***GC-MS market size is close to US$20-25 Million***
- ***All major players own market share between 3-55%***
- ***India's GC-MS business continues to grow 6% CAGR by 2022-2027***
- ***Food, pharma and applied market accounts for major contribution***
- ***Adopting helium conservation steps***
- ***Alternative carrier gas and sustainability.***

Carrier Gas

There is different choice of carrier gas for Gas Chromatography. Hydrogen, Helium, Nitrogen and Argon are the gases that are used in GC as carrier gas with an aim to achieve the best separation in the shortest time. Among these gases, historically helium has been the most widely used in GC-MS due to reactivity with analytes associated with hydrogen and lesser area response with nitrogen for applications demanding lowest quantitation.

Helium crunch

A global helium shortage that began last year continues today and could continue well into next year and disrupt various helium-reliant industries in different ways in making semiconductors and detecting gas leaks in ships.

According to the gas industry, the

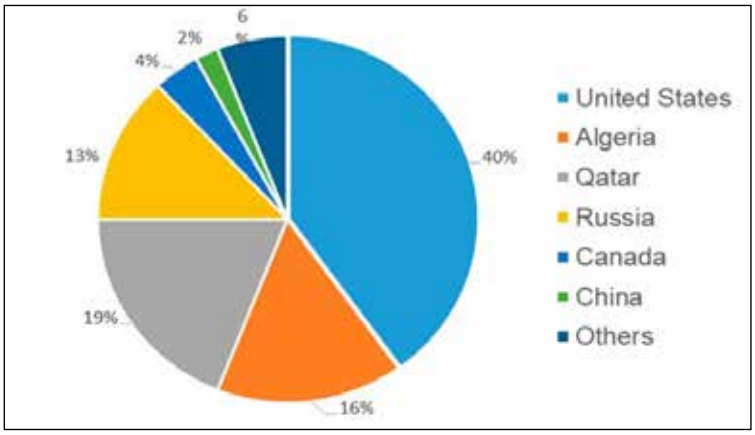


Fig. 1: Countries producing Helium gas [1]

	Helium Carrier Gas	Hydrogen Carrier Gas	Nitrogen Carrier Gas
Pros	• Always the first choice if available • Excellent chromatographic and MS performance • All reference spectra in libraries are obtained with helium	• Best alternative to helium • Better chromatographic resolution and speed compared to helium	• Inexpensive • Widely available in chromatographic grades • Safer than hydrogen
Cons	• Frequent shortages and delivery interruptions • Inconsistent or high costs • Sometimes difficult to find in chromatographic grades	• Requires attention to safety • Requires attention to reactivity	• Requires longer run times to achieve resolution • Not recommended for use with MSD

Table 1 Comparative Evaluation on 3 Carrier Gases

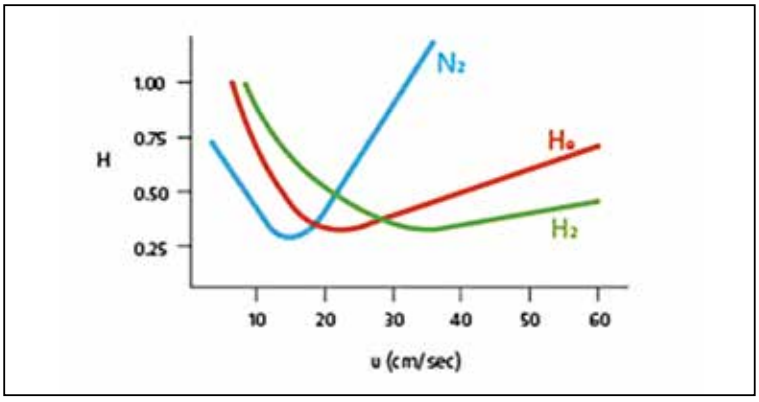


Fig. 2: Carrier Gases and Theoretical Plate Comparison (Van Deemter Equation)

world is currently experiencing 'Helium Shortage 4.0' since 2006 which can be blamed on declining or unreliable production from existing sources.

Helium is one of the rarest elements on Earth, it is difficult to mine, and even more difficult to store. Any helium that escapes cannot be recaptured and vents straight into the atmosphere. Besides being difficult to mine, the current helium shortage stems from the limited supply and rising demand across the world.

Very few countries produce this rare element, so even a minor change in the production levels in these countries can significantly impact the global helium supply. Considering the helium shortage, few practices to be followed to save helium consumption.

Option 1 - Conserve helium

Helium conservation is an easy approach for chromatographers who cannot or do not want to change their GC methods.

Helium Audit - Agilent recommends that laboratories using helium for multiple systems perform a periodic helium use audit and leak check. Record the helium use of each system and calculate the total flow for all systems. Compare this value with the rate at which helium is used from the cylinder that supplies it.

Substitute gas: Some GC-MS systems are not in continues use and can spend a significant amount of time in standby condition. Automatically switching the carrier gas supply to nitrogen during idle time, keeping the flow path inert and the system at temperature while in standby. This process can be automated to prevent interruptions to your GC workflow.

Helium saver: Reducing helium gas on split flow rate at a specified time after the injection while maintaining constant septum purge and column flow rates throughout the GC run. The split flow rate always remains at this lower level except during the injection. Often, the total flow can be reduced by 50% or more[2].

Option 2 – Alternative carrier gas

Efforts have been ongoing to identify alternative carrier gases for Gas Chromatography-Mass Spectrometry (GC-MS) as a substitute for helium. In the mid-1950s, a team of Dutch chemical engineers initiated a comprehensive study focusing on the factors responsible for undesirable peak broadening. This investigation encompassed the examination of various carrier gases and their linear velocities in relation to theoretical plate performance, which is encapsulated in the Van Deemter equation (Figure 2). The goal of these endeavors is to discover and optimize alternatives

such as hydrogen or nitrogen as carrier gases for GC-MS, considering factors like efficiency and analytical performance[3].

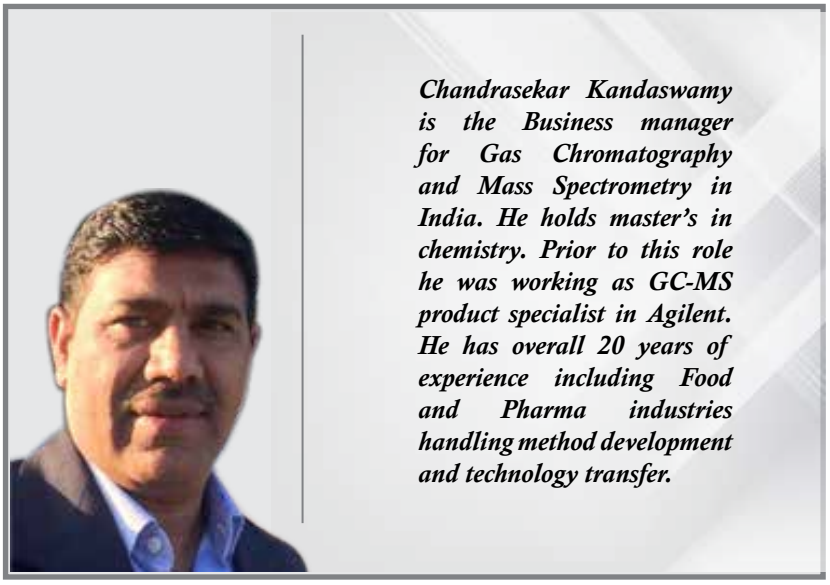
Nitrogen is safe and cost is reasonable, it has disadvantages such as a narrow optimum linear velocity range and a low optimum linear velocity that requires more analysis time.

Hydrogen is also an attractive choice because it is less expensive than helium, is renewable and readily available.

Challenges using hydrogen as carrier gas

Transitioning from helium to hydrogen as a carrier gas in Gas Chromatography (GC) does offer advantages like on-site generation and reduced reliance on external suppliers, but it also presents some significant challenges:

Chemical Reactivity: Hydrogen is not chemically inert, which means it can potentially react with the target analytes, matrix components, or solvents. These reactions can result in compound degradation, peak tailing, distorted ion ratios in the mass spectrum, compromised library matching, and decreased sensitivity. Therefore, careful consideration and optimization of chromatographic conditions are necessary to mitigate these issues.



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Safety Concerns: Hydrogen is highly flammable and poses safety risks in the laboratory. Specialized safety measures, equipment, and training are essential when using hydrogen as a carrier gas to ensure the safety of laboratory personnel and the facility.

Hardware Changes: Transitioning to hydrogen may require modifications to existing GC systems and equipment to ensure compatibility and safety. This can involve upgrading or replacing certain components to accommodate the use of hydrogen.

Chromatographic Conditions: Hydrogen may require adjustments to chromatographic conditions, such as flow rates and temperature settings, to optimize separation and maintain data quality. Method development and validation may be necessary.

Supply Disturbances: While hydrogen can be generated on-site, it's important to have a reliable hydrogen generator in place. Any technical issues with the generator can disrupt laboratory operations, just as supply disruptions with helium would.

In summary, the transition from helium to hydrogen as a carrier gas in GC should be approached with caution and thorough planning (Table 1).. Laboratories should consider safety measures, potential hardware changes, and the need for adjustments to chromatographic conditions. Despite the challenges, the benefits of cost savings and reduced reliance on external helium suppliers make hydrogen an attractive alternative for many laboratories.

> ***Historically helium has been the most widely used in GCMS due to reactivity with analytes associated with hydrogen and lesser area response with nitrogen for application demanding lowest sensitivity. World is currently experiencing "Helium Shortage 4.0" since 2006 which can be blamed on declining or unreliable production from existing sources***

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Gas Chromatography Market Dynamics

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Gas Chromatography, a widely employed analytical technique, is heavily utilized to separate compounds in sample mixtures with heightened precision and accuracy. This is crucial for monitoring product quality, maintaining control over production processes, and assessing packaging materials. Furthermore, the broad acceptance of GC in diverse industries, including oil and gas, pharmaceuticals, food & beverages, polymer characterization, chemical analysis for contaminants, and consumer goods, is driving market expansion. It finds common applications in various scenarios such as determining product constituents, identifying, and quantifying components, and detecting chemical impurities in products.

The worldwide gas chromatography market, as reported by Verified Market Research (*https://www.verifiedmarketresearch.com/product/gas-chromatography-market/)*, had a valuation of USD 2,923.25 Million in 2021 and is anticipated to attain USD 4,623.75 Million by 2030. This expansion is forecasted to take place at a compounded annual growth rate (CAGR) of 5.35% within the period from 2023 to 2030, with Asia-Pacific being singled out as a region experiencing a notably higher market growth rate as represented in Figure 1, while India's growth forecasted CAGR of 7%. In fiscal year 2022 in India, around 1700-1800 standalone GC units were sold including indigenous manufactured GCs additionally with around 350-370 units featuring MS systems along with various sampling accessories. Several factors are contributing to the market's growth, including heightened concerns about food safety, the increasing importance of chromatography tests in the drug approval process, driven by the growing production of petrochemicals, the growing demand for alternative energy sources, and the rising adoption of GC-MS (Gas Chromatography-Mass Spectrometry) in various market segments.

Introduction to Gas Chromatography

Gas Chromatography (GC) stands as a widely acknowledged and influential analytical method employed for the separation, quantification, and identification of vaporizable compounds under specified instrument conditions. It holds significant prominence in the realm of analytical chemistry, primarily due to its inherent strengths, including precise separation capabilities, reproducibility, and expeditious separation processes.

The concept of gas-liquid partition chromatography first emerged in 1952, credited to A. T. James and A. J. P. Martin, researchers hailing from the National Institute for Medical Research in London, though recognition of Erika Cremer for the first reported use of gas chromatography has largely been overlooked due to circumstances of history. This pioneering technique is typically attributed to these inventors, as detailed in their 1952 publication in the Biochemical Journal. Within this seminal work, they extended the theory of the partition column to encompass a mobile phase that can undergo compression. Furthermore, the publication outlined the application of gas-liquid partition columns for the separation of volatile fatty acids. Remarkably, Martin and Synge jointly received the Nobel Prize in Chemistry that same year for their

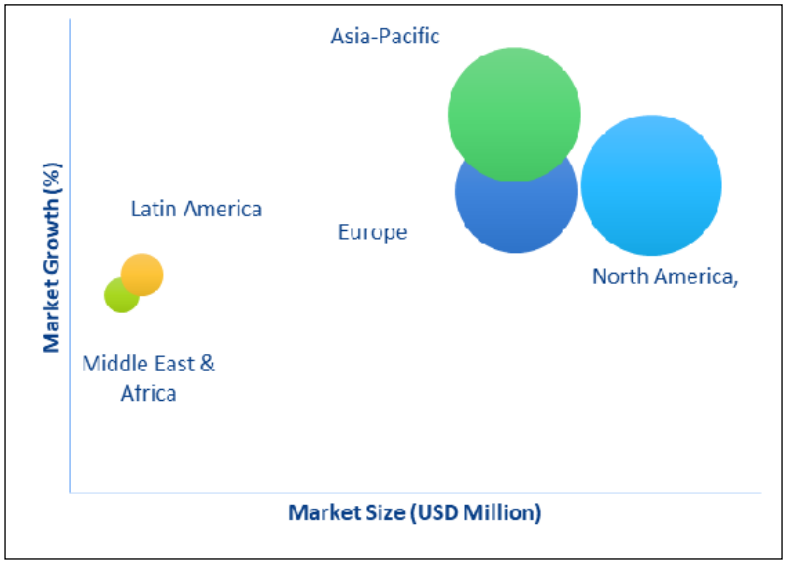

Fig. 1: Marker growth representation of GC

groundbreaking contribution to partition chromatography.

The inaugural commercial gas chromatograph was introduced in 1955, marking a pivotal moment in the evolution of this analytical method. Over the ensuing years, gas chromatography has diversified into various specialized techniques, including capillary gas chromatography, gas-solid chromatography, and gas-liquid chromatography. Presently, gas chromatography ranks among the most extensively employed investigative methods in instrumental analysis.

Market segments with potential demand in India

One of the primary reasons for the GC market's optimistic outlook in India is the notable expansion observed in numerous industries within the market segment.

Pharmaceutical

Pharmaceutical sectors employ volatile impurity profiling to assess organic impurities linked to processes and drugs. These impurities can potentially emerge during drug substance manufacturing or storage. Typically, starting materials or intermediates are the prevalent impurities in active pharmaceutical ingredients (APIs) unless meticulous measures are taken at each stage of the complex synthesis process. To detect genotoxic, mutagenic, and carcinogenic impurities, pharmaceutical industries utilize GC or GC-MS systems. Notably, the list of compounds subject to scrutiny continues to expand, with Nitrosamine compounds added in 2019, whether present in the API or the final product.

Residual solvent analysis within the pharmaceutical field pertains to the examination of organic volatile impurities that emerge as byproducts during the synthesis of pharmaceutical drugs or their utilization in manufacturing processes. In accordance with Good Laboratory Practices (GLP) standards, it is obligatory for pharmaceutical manufacturers to ensure that these residues are either eliminated or present in only minimal concentrations within the final products and measure as per the ICH (R8) guideline and represented chromatogram for class 2 solvents in Figure 2.

An increasing worry regarding packaging materials centers on the migration of chemical compounds from pharmaceutical packaging into the pharmaceutical products themselves. These substances are commonly known as extractables and leachables. Therefore, it

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- *In the fiscal year 2022, India saw the sale of approximately 1700-1800 standalone Gas Chromatography (GC) units, with an additional around 350-370 units configured with Mass Spectrometry (MS) systems.*
- *The promising outlook for GC in India can be attributed to the expanding manufacturing sector and the significant shift towards alternative fuels, particularly the adoption of biofuels and hydrogen.*
- *Several reports indicate that the Asia-Pacific region is experiencing a higher GC growth rate, with an anticipated annualized Compounded Annual Growth Rate (CAGR) of 7%, surpassing the global GC growth rate of 5.35%.*

is crucial to take measures to minimize the presence of organic impurities, residual solvents, and extractables/leachables. Achieving this goal, particularly in the context of researching new compounds, necessitates the use of various instrumental techniques, including gas chromatography (GC) with an appropriate detector and mass spectrometry (MS) systems, to meet the analytical requirements.

Food Quality & Safety

The global food industry, encompassing agriculture, manufacturing, production, processing, research, and development, among other sectors, stands as one of the largest segments of the worldwide economy. As this industry continues to advance, it has adapted to address diverse global demands and requirements. Within the food & beverage sector, gas chromatography plays a crucial role in various applications, including the analysis of low chain fatty acids, aromatic components, the composition of food & beverage constituents and identification of off-odor compounds.

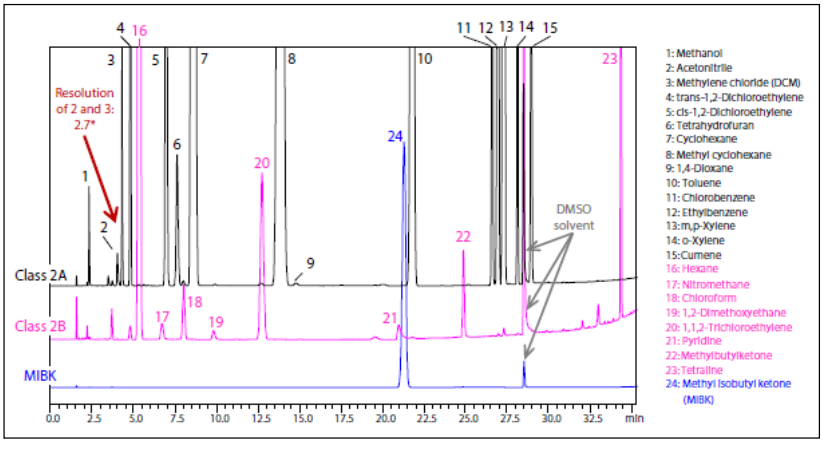

Fig. 2: Chromatogram of Class 2 Standard Solution as per <USP 467> method

Moreover, dairy products enjoy widespread consumption on a global scale. To ensure the quality and purity of milk, ISO 17678:2019 introduced the GC-FID method for analyzing milk fat integrity, which is now a mandatory measurement for all milk and milk-related products.

The increasing emphasis on food safety has led to the adoption of rigorous regulations aimed at guaranteeing the safe consumption of various food products. These regulations encompass a wide array of compounds, including pesticides and herbicides, and are regularly updated based on the toxicity of these substances. This focus on monitoring has expanded to include a broader range of agricultural and herbal products, thereby driving the demand for hyphenated GC with triple quadrupole MS systems in the market.

Flavor & Fragrance

Flavors are employed as additives to elevate the taste of food & beverages in various applications, including bakeries, snacks, dairy products, sauces, and confectionery. Likewise, fragrances play a crucial role in masking undesirable odors in the environment and are primarily utilized in consumer goods such as body care products, oral care items, and household cleaning products. These substances are incorporated into products to enhance their appeal by altering the characteristics of the solute, such as providing pleasant aromas or imparting various taste profiles, including sweet, sour, tangy, and more. Flavors and fragrances can be derived from natural sources, synthetic chemicals, or essential oils like vanilla pods, citrus fruits, beaver castor, and deer musk. The identification and measurement of constituents in flavors and fragrances are typically carried out using the GC and GC-MS techniques.

Environmental Testing

Environmental testing is of paramount importance in advancing sustainable development, as

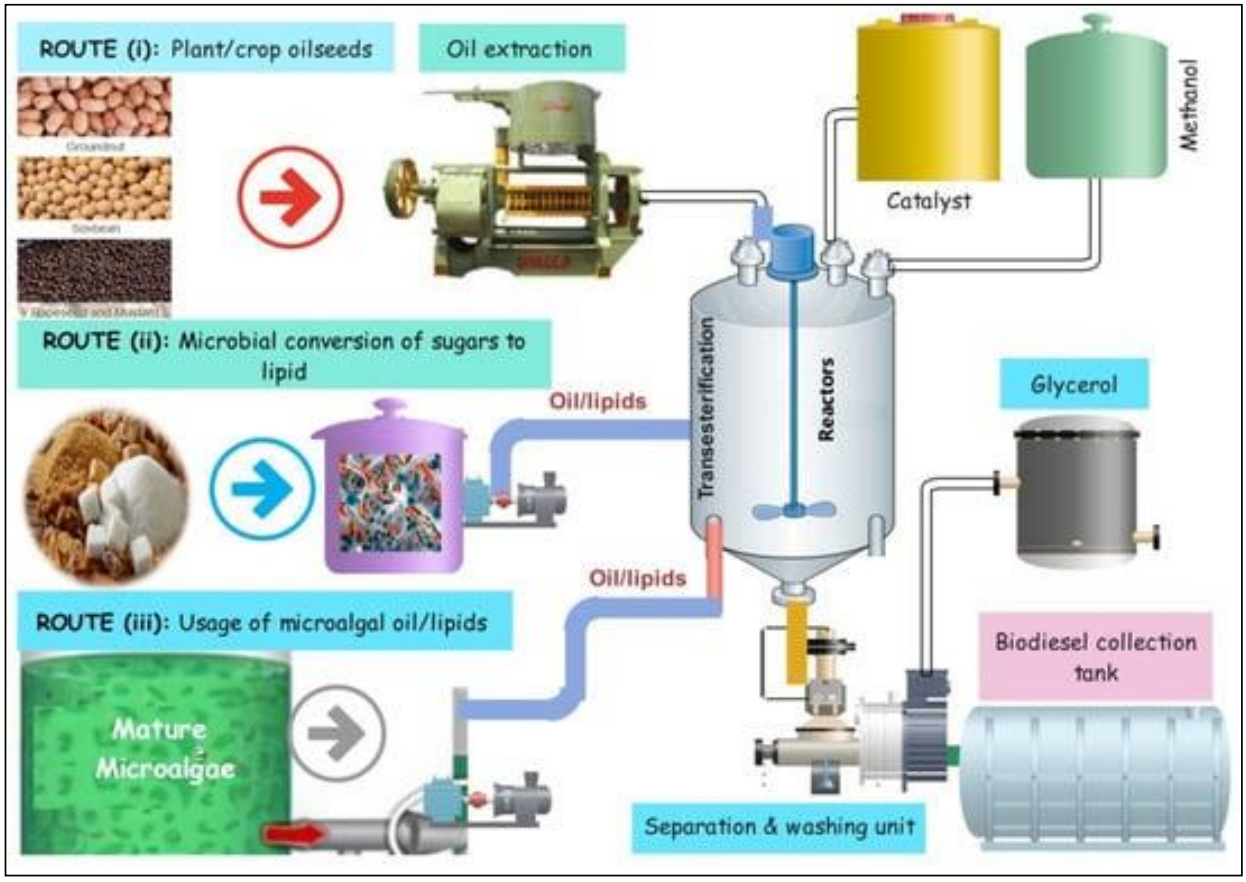

Fig. 3: Biodiesel production via the transesterification process

it involves the evaluation and surveillance of human activities' effects on the environment. This process encompasses the examination of diverse environmental elements, including the atmosphere, water bodies, soil, and potentially harmful substances. Its primary objective is to pinpoint potential hazards and verify adherence to regulatory guidelines. Public health protection heavily relies on maintaining high standards for water, soil, and air quality, with routine assessment parameters such as TPH, PAH, aromatics, VOCs, and pesticides, among others, being quantified through various analytical techniques. Gas chromatography stands out as a crucial method for meeting the stringent requirements of environmental testing.

Consumer Product Testing

Consumer product testing represents a significant opportunity for Gas Chromatography measurement. In recent years, India's manufacturing industries have experienced substantial growth, particularly in the production of electronic, electrical, automotive, household consumer goods, and related accessories. Various instrumental techniques have been employed to assess product quality and identify the presence of potentially hazardous chemical substances. These products are subject to regulations concerning the Restriction of Hazardous Substances, encompassing various compound categories. The International Electrotechnical Commission (IEC) has issued IEC 62321 as a method for quantifying these compound groups either by solvent extraction followed by GC with MS to detect volatile impurities or a screening method utilizing a Pyrolyzer accessory, adopted due to the complexity of products with multiple components.

Chemicals & Petrochemicals

The petrochemical and chemical industry extensively utilizes Gas Chromatography across all stages of the petroleum sector, ranging from crude oil exploration and refining of end products to the exploration of new petrochemical compounds. Given the diverse and intricate nature of the samples involved, petroleum chemists employ a wide range of gas chromatographic techniques, both in laboratory settings and within the industrial processes. India holds a prominent position as a major exporter of petroleum products, encompassing refined petroleum, naphtha, and liquefied petroleum gas (LPG).

GC techniques provide versatile solutions for the identification, characterization, and quality assessment of specialty chemicals such as polymers, plastics, films, dyes, pigments, paints, inks, adhesives, textiles, surfactants, among others. Furthermore, GC contributes significantly to the innovation and development of novel chemical products.

The significance of alternative fuels in replacing conventional fossil fuels has grown considerably due to the need to reduce greenhouse gas emissions and protect the environment. Concerns have been mounting about the use of fossil fuels, including increased oil imports, rising levels of air pollution, higher CO_2 emissions, and the depletion of mineral oil reserves like gasoline and diesel. To address these issues, the Government of India has outlined a plan to reduce its reliance on crude oil imports by 10% by 2021-22 and decrease energy emissions intensity by 33%-35% by 2030, in alignment with the Nationally Determined Contribution (NDC) targets established during COP21 in Paris. This plan involves boosting natural gas production, promoting energy efficiency and conservation, emphasizing demand substitution, harnessing the untapped potential of biofuels and other renewable energy sources, and implementing refinery process improvements. To achieve these goals within the specified timeframe, various alternative fuel options are being considered, and this section provides descriptions of a few of them.

> ***Gas chromatography ranks among the most extensively employed in numerous industries – pharmaceutical, food quality & safety, flavor & fragrances, environmental testing, consumer product testing, chemicals & petrochemicals, clinical & toxicology etc.***

Biodiesel represents an alternative fuel with diesel-like characteristics, produced through a straightforward chemical reaction involving alcohols and vegetable oils as represented in Figure 3. Typically, it is derived from sources such as non-edible vegetable oils, used cooking oil, animal fat, and bio-oil. Nevertheless, in India, the preference leans towards non-edible tree-borne oil seeds like Jatropha and Karanjia. To assess the composition of biodiesel and its components, such as FAME (Fatty Acid Methyl Ester) and Triglyceride composition, established EN (European Norm) methods are employed, with Gas Chromatography serving as a vital tool in the analytical process.

Hydrogen emerges as the fuel of the future for promoting eco-friendly transportation. It serves as an outstanding energy carrier, holding significant promise for clean and efficient transportation solutions. When integrated with fuel cell technology, hydrogen becomes a pivotal component in achieving a well-rounded energy mix for environmentally sustainable transportation. This transition not only enhances energy security but also reduces reliance on oil, lowers greenhouse gas emissions, and mitigates air pollution.

To ensure the efficient production and utilization of hydrogen as a fuel by several means is represented in Figure 4, it is imperative to closely monitor its quality and productivity. This involves adhering to standards which specifies permissible impurity levels in hydrogen fuel. The analysis of hydrogen fuel quality necessitates specialized gas chromatography

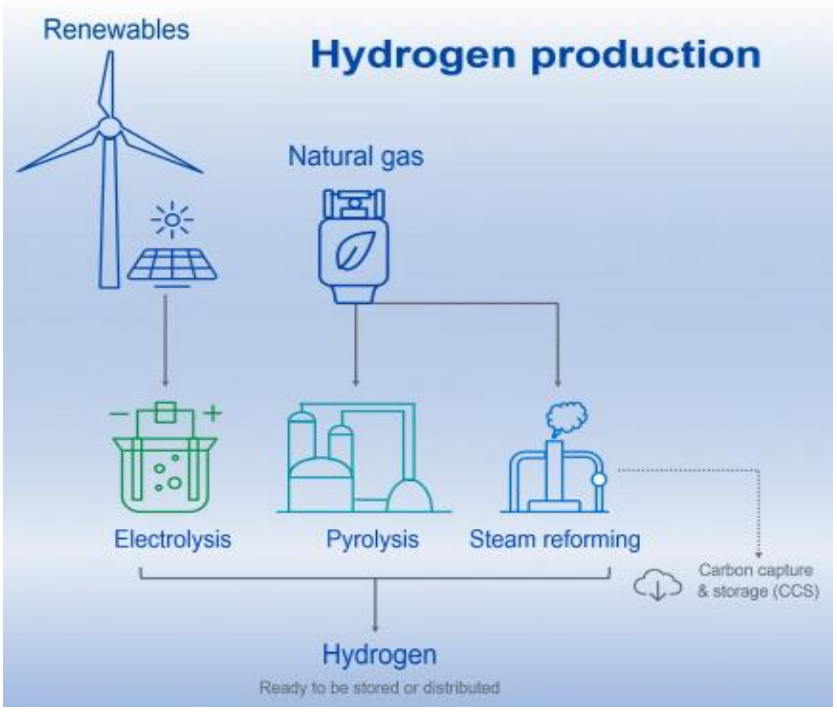

Fig. 4: Hydrogen production

Fig. 5: VUV detector from VUV Analytics

instruments with various detectors to meet specific requirements. This imperative aligns with the global agenda to reduce the intensity of energy-related emissions, driving the demand for advanced GC technologies.

Clinical & Toxicology

In addition to the previously mentioned market segments, there is growing interest in applying metabolomics studies on plants/agriculture farming aimed at prolonging the shelf life of agricultural produce and has garnered attention in clinical applications such as inborn errors of metabolism detection. Forensic toxicology application gained interest, particularly in cases involving blood alcohol levels and the identification of psychotropic drug substances. It is expected that these application segments will receive increasing attention in the years to come too.

Recent Advancements in Instrumentation

Gas chromatography is a well-established and robust chromatographic technique that has evolved over time to cater to various application fields by incorporating improvements in injector ports, detector ports, accessories, and a wide range of stationary phases. In recent years, the integration of AI-based automation into these techniques has significantly enhanced the generation of results and data. Several well-regarded manufacturers of GC equipment have incorporated automated functionalities such as self-diagnostic tools, baseline monitoring, system suitability test etc., that prioritize the convenience of analysts. An ongoing Helium shortage is causing significant worry among numerous gas chromatography customers today. An approach involves switching to Helium gas during analysis and automatically transitioning to a different gas type once the analysis is finished and switching the instrument to standby mode to minimize helium gas usage.

VUV Analytics introduced a novel detector based on absorption spectroscopy within the vacuum ultraviolet (VUV) region of the electromagnetic spectrum. This cutting-edge technology has garnered attention for its ability to capture highly detailed gas phase absorption spectra, which prominently feature vibrational and rotational transitions. The primary advantage of employing VUV spectroscopy as a detection method lies in its universal applicability, while also providing valuable qualitative data.

Recently, this detector has gained significant traction, particularly in the fields of petrochemical and fuel analysis. Numerous ASTM methods have been developed to leverage the wealth of information it offers compared to conventional systems. Additionally, researchers are actively exploring the potential of VUV detectors in diverse application areas, such as forensic analysis and drug testing.

Prominent companies in the industry include Shimadzu Corporation, Agilent Technologies, PerkinElmer Inc and Thermo Fisher Scientific Inc., among the imported brands of GC. Some of the indigenously manufactured brands of GC including Netel Chromatograph; Nucon, CIC etc. cater to certain market segments. Global manufacturers like Teledyne, Markes International, CTC Analytics, Restek Corporation, Phenomenex Inc., Sigma-Aldrich etc., cater to various aspects such as sampling accessories, GC columns, and GC consumables.

Conclusion

The gas chromatography industry is experiencing consistent growth due to an increased emphasis on research and development and a heightened commitment to quality standards. This growth is primarily attributed to the rising demands from rapidly advancing sectors such as pharmaceuticals and life sciences, as well as from various other industries including energy & chemicals, petrochemicals, environmental management, and food production, among others. The manufacturers are enhancing their product offerings by introducing new and improved designs and specifications, thereby providing enhanced solutions to meet customer requirements to ever demanding analytical requirements. Anticipated advancements in technology and product innovations are poised to accelerate the growth rate of the instrumentation industry. India, recognized as a favored location for numerous multinational corporations to establish their research and development operations, is poised to witness significant growth in this particular sector.

Laboratory Automation, for Enhanced Productivity and Regulatory Compliance

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The recent work towards the creation of modern medicines and innovative research is rewarding humanity with longer and healthier lives. Scientists across global laboratories are now collaborating more often to hasten the research. More companies are now outsourcing manufacturing rather than making the products on their own. Consumers are becoming more aware of their health and are now conscious about what they eat. Not only are they getting more concerned about whether the food they eat is contaminated or not, but also whether it is authentic. They are also proactively taking measures and making food choices to stay healthy. There is a greater awareness about the well-being of our environment. Citizen groups and associations are now challenging the age-old ways of the industries that are degrading the environment. All these scenarios have necessitated the setting up of newer laboratories, with ever-increasing samples to be analysed and more personnel to man these laboratories.

The laboratories address newer requirements with modern and sophisticated instruments. But everything is not hunky dory. There are challenges that scientists and laboratory managers must face.

- More analytical instruments and scientists are required to reduce turnaround time. But there is also a pressure to do more with less i.e., spending on instruments and new hires are curtailed. The laboratory managers are expected to deliver results with cuts in budgets.

- The advanced instruments used in modern laboratories like UHPLC and Time-of-Flight mass spectrometers are generating humongous amounts of data. This data must be available to scientists for collaboration across sites. This data must also be stored in a manner that meets the regulatory requirements. The data must be stored for an extended time and must be retrievable quickly on demand. There are ever-growing requests that the collected data be available for analytics and dashboards. This data must also be available in a universal format because scientists are now using a wide variety of tools to look at trends, find new insights and perform predictive analysis.

- The laboratories are generating ever-growing heaps of paper-based results, reports, and summaries. The management of paper is inherently problematic. Over longer periods paper degrades and becomes unusable in some cases. It is difficult to search and sort data stored in paper reports. I have known incidents where scientists have told me that sometimes it is easier to repeat the experiment rather than spend time searching documents and notebooks that contain the conducted experiment in the past.

- The workflows related to sample management and execution of tests and experiments are managed with a paper trail. This is not the most efficient way of managing laboratory workflows. And certainly, does not help in the mantra of doing things right the first time.

- The 'use by' date and reconciliation of chemicals, standards and solvent usage is managed in paper notebook-based inventories. The same is true for instruments used for testing samples. The calibration and maintenance schedules are managed in paper notebook-based inventories. It is easier to overlook whether the chemicals and instruments are in their usable time. These errors are normally detected at the far end of the process when the testing is completed and results are reviewed.

- Non-integration of data systems i.e., data generators like analytical instruments and data consumers like data management systems and analytics tools, induces data transcription. This makes the

overall process slow, and prone to failure due to transcription errors. In a compliant environment, this is a sure way of inviting adverse comments from an auditor. Management of data in silos discourages teamwork.

- The regulations are getting stricter and audits getting more frequent and punishing. The data generated in the laboratory must follow the requirements mentioned in regulatory guidelines. More manual processes lead to more errors and non-compliance.
- Employee turnover is at an all-time high. The managers must hire quickly and get the scientists and analysts trained so that productivity is not hampered.

The laboratories have responded to these challenges in myriad ways. However, if the manual processes and transcriptions are not eliminated, the results are bound to be poor. The need of the hour is to make the laboratory workflows electronic.

The steps that can be taken, not necessarily in this order, to overcome these challenges are:

- Create a centralised electronic repository with an index or catalogue, of all the data generated in the laboratory. This will make data searching and trending easier. This will also aid collaboration between teams that are isolated geographically. This repository can also act as a middleware for exchanging data electronically between data-generating systems and data-consuming systems.
- If available, do the calculations within the software application where the data is generated and not move it manually to another application for generating final results. Use limit checks with calculations to help in exception review of results. This will greatly reduce the turnaround time in the laboratory.
- Reduce or eliminate the transfer of data from one software application to another. Ensure that the data transfer is done electronically from one application to another. This will eliminate the re-keying of data. This will also eliminate the associated additional steps of assigning reviewers the task of reviewing the re-keyed data. Integrating the systems and moving the data electronically will reduce validation efforts, reduce manpower, reduce turnaround time and make the workflow free from errors and more compliant with regulatory guidelines.
- Reduce paper usage or eliminate it. If your computerised data system controlling and collecting data from analytical instruments allows it, sign off results electronically and save a copy of the signed-off result within the computerised system. In case your computerised system does not have the capability of electronically signing results, then save electronic copies of results and reports in the centralised electronic repository. Then set up an e-signature workflow in your repository. Review, approve, and sign off results electronically

Chandresh has a long career of more than 30 years, working in the Analytical Instruments industry. He started as a service engineer, where he worked with a wide variety of instruments. Apart from servicing instruments, he gained insight into QC lab operations during these initial years.

He joined Waters in 1999. He was promoted to the position of Product Manager - Data in 2001. The role involved understanding regulatory compliance and lab efficiency challenges faced by QC labs, and how these could be addressed with Waters Empower Chromatography Data System software.

He spends a lot of time reading various guidelines published by US FDA, UK MHRA, WHO and other such regulators. He also reads Warning Letters, 483's and Notices of Concerns. He has been a speaker on Waters Informatics solutions, regulatory compliance and data integrity at many pharmaceutical companies and events sponsored by Waters.

in the centralised repository. There will be huge savings on paper and printing. Storage spaces and storage devices can be eliminated or reduced. The saved space can be repurposed for some other usage. The teams of archivists that were required earlier to store and retrieve paper records will not be required anymore. The indexed data in the electronic repository can be found easily and on time. This is especially important in audits. The records and data that cannot be found when most required, in a reasonable amount of time are deemed not available and may invite adverse comments from the auditors.

- Simplify workflows and use software tools to track samples and test results. Include bar codes, bar code readers and dropdown lists in the electronic process to reduce manual entries.
- Collect data from small devices electronically. Eliminate manual transcription of readings from devices.
- Create electronic inventories of instruments and chemicals. Integrate these inventories with workflows to ensure that the right instruments and 'good to use' chemicals are used.
- Create soft copies of Standard Operating Procedures, maintain electronic records of training, and integrate the same with laboratory workflows.

There are a host of automation tools available today to implement the steps outlined earlier. Depending upon the type of laboratory, and the regulations (or no regulations) that govern your data, you may need some or most automation tools. Some of the most commonly available tools are listed here. This is not an exhaustive list of solutions available to laboratories.

> ***Laboratory automation tools enable scientists to work more efficiently, thereby increasing productivity and enhancing regulatory compliance. A few key automation tools such as Laboratory Information Management System (LIMS), Scientific Data Management System (SDMS), Electronic Laboratory Notebook(eLN), Document Management System (DMS), etc have revolutionised automation of various processes in the analytical labs resulting in better compliance coupled with increased productivity.***

Scientific Data Management System (SDMS)

This is sometimes also called a Content Management System. SDMS is an automated electronic repository that stores and manages all types of scientific data (machine-readable and human-readable) in a centralized database. Using automated tools, SDMS captures and stores the critical scientific data generated by any instrument or application. It then automatically catalogues the data, with no manual intervention by analysts. The analysts can quickly locate and retrieve information. The users benefit by eliminating printed reports, seamless data integration to LIMS, electronic laboratory notebooks and other information management systems.\

Laboratory Information Management System (LIMS)

A LIMS is a software tool that allows you to track samples and results very effectively. Modern LIMS go much beyond sample tracking. They now have additional modules that can automate workflows, integrate instrumental results, facilitate the execution of tests, provide inventories, manage training records, workflows for out-of-specification results and dashboards. And the list keeps growing based on user requirements.

Enterprise Resource Management (ERP)

An ERP is a software tool that companies employ to manage day-to-day business activities. Some ERP solutions offer modules to manage pharmaceutical drug testing. There is a school of experts that believe ERP can do most of the LIMS functions and more. I will not comment on this and let the debate continue.

Electronic Laboratory Notebook (eLN)

An eLN is a document authoring tool. It is a platform for documenting the performance of tests, experiments and collaboration in the laboratory. It replaces traditional, static, paper-based record-keeping with a dynamic, electronic system that makes information easily available and organizable. eLN facilitates reliable

data collection from both simple devices like an analytical weighing balance and complex instruments controlled through a computerised system. It includes comprehensive search capability and efficient signature management. eLN dramatically improves information management and lab operations of both - regulated and research and development (R&D) areas alike. Most eLNs include inventories and analytics tools.

Laboratory Execution System (LES)

A LES is an automation tool that supports test execution for product testing in a pharmaceutical Quality Control laboratory. In a true sense, it is an electronic laboratory notebook that is optimised for Quality Control testing.

Document Management System (DMS)

A DMS is a computerized system used to store, share, track and manage documents. It includes tracking changes where a log of the various versions created and modified by different users is recorded. Almost always, it is used to create and manage standard operating procedures.

Learning Management System (LMS)

An LMS is a software application for the delivery, documentation, tracking and reporting of training, and development programs. It is desirable that LMS is integrated with eLN or LES so that only trained and certified users are allowed to perform the material testing.

Laboratory Management System (LMS)

An LMS uniquely combines synergistic data, workflow, and sample management capabilities. It is a user-centric platform that encompasses SDMS, a compliant-ready data repository, a flexible analytical electronic laboratory notebook, Inventories, and Sample Management. It seamlessly links data from the lab to the business operations of the enterprise.

Now that the laboratory managers are aware of their challenges and the steps to be taken, how can they move forward? How can they narrow down their choice of vendor and software solution? This is easier said than done. Here are some guiding principles to make this task easier.

- The truth is there is no single software solution that is available that will address all the challenges. The laboratory must rely on multiple software solutions.
- Choose vendors that have experience just not in building software solutions, but also have a thorough understanding of analytical instruments, laboratory workflows and regulatory requirements.
- First, choose a software solution that solves the greatest number of challenges or a vendor that supplies most software solutions. This will ensure that you deal with fewer vendors. This will reduce software integration challenges and deployment costs. You will spend less on annual maintenance plans and upgrades.
- In case it becomes inevitable that you must rely on more than one vendor for software solutions, ensure that your vendors have long working partnerships. Ensure that they have an out-of-the-box Application Program Interface (API) for the exchange of data between their supplied software solutions.
- Automation projects are rarely completed in less than 3 to 6 months. There are unanticipated delays and cost spillovers. These projects require qualified project managers, domain experts and full-time support engineers for successful deployment. So, choose a vendor that has the required resources on their payrolls.
- When new instrument purchases are planned, ensure you choose the ones that come with computerised system software that complies with regulatory requirements, allows you to do the final calculations, makes reports that allow electronic signoffs and can share results in the most publicly available formats. Do not make compromises and invest in instruments that give a visual display of the readings and test results.

The desirable goal is that these laboratory automation tools will enable scientists to work more efficiently, thereby increasing productivity and enhancing regulatory compliance. Overall, this will hasten the pace of discovery, and allow more samples to be analysed, more accurately.

Pharma Digital Transformation – The India Story

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The Indian pharmaceutical industry has achieved a significant global position and has witnessed phenomenal growth in recent years. To set the stage, India is the 3rd largest pharmaceutical market in terms of volume and 13th largest in terms of value and is expected to grow further rapidly in coming years[1]. The industry covers generic and branded pharmaceuticals, vaccines, and medical devices. India is emerging as a major vaccine supplier with 60% of global needs being produced in India and as a world leader in generic pharmaceuticals production, supplying 20% of the global market for generic medicines.

For over the past two decades, Indian Pharmaceutical sector has been in a leading position in the global landscape. With a current market size of around US$ 50 Billion, India exports to nearly 200 countries including highly regulated markets of the USA, European Union, Canada, and UK, India is rightly now known as the "Pharmacy of the World"[2].

According to the Economic Survey of 2020-21, the Indian pharma industry is expected to expand to US$ 65 Billion by 2024 and approximately US$ 130 billion by 2030[2]. The COVID-19 pandemic gave India both an opportunity and a challenge in its quest to become the global pharmacy hub.

> ***Digitalization is not just a helping hand for efficiency, it is a growth driver for pharma companies***

The Evolution of Pharma Digitalization

For the past decade, the pharma industry has been growing close to 10% CAGR and is expected to grow much more in the next few years. To meet the market demand, pharma companies had to increase production capacity through expansion, outsourcing, and modernization. Pharma being a highly regulated industry, always looking at a patient safety-centric approach, quality of the medicines delivered to the market is expected to meet quality standards to 100%. Even when the production is outsourced to a contract manufacturing unit, quality responsibility completely lies with the company. There is an important statement very familiar in the industry to that effect, "*A company can never outsource quality*." Therefore, regulators and regulations have been becoming more demanding based on the changing market dynamics.

Earlier, regulatory audits focused on drug release testing and related practices to assess the quality standards of release. In Early 2000s, the US federal government introduced federal rule on Electronic Signatures and Electronic records (21 CFR part 11), which was adopted by US FDA to accelerate the adoption of technology in Pharma manufacturing to assure timely supplies of medicines, that triggered digitalization of Quality control operations. Laboratory Information Management (LIMS) market started growing quickly from that point of time.

Tier one and other progressive companies started adopting LIMS for Quality Control operations from early 2000, but the industry adoption was slow, and it was limited to a focus on reducing paper-based documentation.

Subsequent triggers for digital adoption

A series of triggers over a decade accelerated technology adoption.

Increasing drug availability need, stirring innovation, and reaching faster to the market along with the necessity to curb the risks

of regulatory inconsistencies led to the digitalization drive in the pharmaceutical industry. The need for automated handling of activities – from research to manufacturing, testing, packaging, and delivery under tightly controlled parameters projected an increase in the use of digital technology.

Traditionally relying on manual operations, the Indian pharmaceuticals took a giant leap towards digitalization to match pace with the changing market dynamics. To serve the connected world through continuous innovations, judicious adoption of new technologies emerged to be an uncompromised venture.

Data integrity focus

Stringent global regulatory audits around 2014 brought out system vulnerabilities causing questionable data integrity. The majority of the Data Integrity (DI) issues were attributed to human errors and procedural lapses. This triggered a new regulatory guideline called ALCOA, which stands for Attributable, Legible, Contemporaneous, Original, and Accurate of every operation that is documented. This triggered a great demand for digitalization across the GMP operations. LIMS adoption significantly grew after this point.

Substantial Rise in the Bar of Regulatory Compliance

The increased prevalence of chronic diseases and the outbreak of unprecedented healthcare emergencies has made regulatory bodies more vigilant. The regulatory pathway regarding manufacturing process and safety, efficacy, and quality aspects for similar biologics has been narrowed down. Stringent compliance requirements have paved the way for quality control processes and safe drug products.

With the introduction of surprise FDA inspections and free flow of information on social media, organizations must be attentive of their digital initiatives.

The Role of Quality in Healthcare

Amidst catering to the growing needs of the regulated market, quality adherence became more essential. While digitalization accelerated healthcare activities and care delivery, regulatory inspections levelled up to ensure patient safety.

Quality Assurance: With quality control measures, laboratories and healthcare manufacturers could develop drugs that were safe to consume. However, inconsistencies in healthcare delivery persisted. FDA audits discovered procedural glitches and pitfalls which led to increased warning letters. An unexplored aspect came into picture – Self Governance. Regulatory bodies put in a lot of time and effort to ensure compliance within labs and manufacturing facilities.

Sekhar Surabhi is the Founder of Caliber Technologies, one of the leading IT solution providers for regulated industries. Sekhar's passion is to create simple solutions for complex problems. This has been his driving force behind envisioning a pathdefining Integrated Quality Management model with Caliber's product suite.

Prior to founding Caliber, Sekhar worked extensively in analytical instrumentation and pharmaceutical core testing in senior leadership roles. He specializes in managing the integrity of critical applications in highly regulated environments. Sekhar is the functional architect of CaliberLIMS, which addresses the Quality Control needs of regulated industries. With his vision of Integrated Quality Management, Caliber offers solutions that automate and digitally transform processes in Manufacturing, Quality Assurance, and Data Insights. Under Sekhar's leadership, Caliber has been the recipient of several awards of excellence; and he was also conferred with the Entrepreneur of the Year Award by HMA. Most recently, Caliber's visionary product, 'Anytime Product Quality Review', also won an excellence award. Sekhar is currently a Director on board of ISPE India (International Society for Pharmaceutical Engineering).

This also led to discovering inconsistencies more often, further leading to escalations, 483s, and negatively impacting pharma businesses. This triggered a need for automating complete Quality Management Sytems, to establish a self-governance within GMP operations. Indian pharma industry extensively adopted Quality Management Systems, Document Management Systems and Learning Management Systems.

Quality Metrics: Around 2015, regulators wanted to introduce risk-based audits of the manufacturing sites based on the maturity of the quality systems the company follows. FDA introduced draft guidelines for Quality Metrics, where a company's quality maturity is measured through a set number of parameters like process capability index to rate a company. Better index will attract lesser surveillance. This triggered another wave of need for digitalization, as process capability index can only be derived quickly from the data available in electronic form.

Digitalization as a growth driver

In the landscape of pharmaceuticals, quality is a standard requirement, not a differentiator. That is why several expectations are set for this industry to ensure that quality is maintained. With regulators, governments, and the industry working towards ensuring patient safety, there are many boxes to tick for a pharma company before a drug goes to market. Without the right systems in place, these checkboxes can slow things down for a company, delaying time to market. As a result, in this thriving industry, competitive advantage may be lost. Digitalization is not just a helping hand for efficiency, it is a growth driver for pharma companies.

It is interesting to note that last year FDA fines and fees on the manufacturers amounted to US$ 13.5 Billion. These were mostly due to delays in supplying the goods to the market. 621 drug shortages were traced back to Quality issues or Manufacturing issues. This increased the need to reduce the time to market through digitalization.

Upsurging Demand for Medicines and avoiding drug shortages

The past decade has seen a dramatic increase in medicine demand. Changing lifestyles, over-the-counter drugs, and growing population greatly impacted the pharmaceutical businesses overall. Medicine use, specifically daily doses, has grown by 36% in 2022 and is projected to reach a total of approximately 3.4 trillion doses by 2027, the highest volume growth expected in Latin America, Asia, and Africa[3]. This exponential growth in drug demand has triggered the need for better healthcare investment and faster reach to the markets. This is one of the most prominent drivers for digitalization.

Digital Manufacturing Systems and Pharma 4.0: With the need to accelerate the pace toward the market with quality products, the healthcare industry pitched in automated manufacturing systems for electronic batch recording, logs, and in-process quality controls. Advanced manufacturing technology and tools assured the healthcare sector to expedite batches while also maintaining data integrity and compliance.

Data Visibility & Trend Management Systems: Lifesciences industry generates huge volumes of data, which makes it more possible to tackle digitalization. Deriving value from such data poses a realistic expectation to drive further growth in the healthcare industry. Integrating healthcare solutions with quality analytics tools marked a progressive transformation for businesses for informed decision-making.

Remote audits capability

Covid pandemic triggered an unprecedented need for medicine amid travel restrictions. Regulators had to ensure an uninterrupted supply of quality medicines through remote audits. This triggered a great need for automated systems that can be remotely accessed to ensure drug safety. Post Covid too, the FDA and other agencies want to rely on remote audits to increase the number of audits they can conduct, thereby ensuring extensively monitored drug supplies.

Digitalization is not a one-size-fits-all fix. However, it has significant potential to improve primary research and care KPIs leading to patient safety. With automated laboratories and research centers, drug discovery and testing procedures are accelerated, leading to reduced time to market, increased agility, higher and faster ROI. The automation of tedious tasks in medical organizations can increase experienced staff productivity and lead to improved supply chain management. Expanding digital technologies in the healthcare industry further decreases inventory costs, improves delivery time and tracking, promotes patient safety, and develops a lean supply chain.

Pharma 4.0: A Paradigm Shift

In recent years, India's pharmaceutical industry, renowned as the "pharmacy of the world," has experienced a profound transformation. The emergence of Pharma 4.0 marks a significant paradigm shift, embodying the fusion of cutting-edge technologies and data-driven processes in pharmaceutical manufacturing and development. It fundamentally redefines how drugs are discovered, developed, and delivered to patients.

Pharma 4.0 represents more than just a digital technology approach; it signifies a fundamental shift

in mindset. Manufacturers are tasked with discovering innovative methods for problem-solving and harnessing advanced technology to enhance efficiency and compliance. This shift places humans at the core of Pharma 4.0, emphasizing the importance of connecting workers, introducing more human-centric workflows, and fostering a culture of continuous improvement. Digitalization alone does not suffice.

Within this transformative landscape, the pharmaceutical industry harnesses advanced analytics and extensive data, enabling expedited, well-informed decision-making. Artificial Intelligence (AI) and Machine Learning (ML) play pivotal roles in drug discovery, predictive analytics, clinical trial optimization, and the development of personalized treatments through patient data analysis. The Internet of Things (IoT) ensures pharmaceutical product quality and patient safety by vigilant monitoring across the supply chain. Blockchain technology bolsters transparency and traceability within the pharmaceutical supply chain, thwarting counterfeiting and affirming drug authenticity.

This marks a significant shift in the pharmaceutical landscape, driven by the principles of Pharma 4.0.

Future Trends in India's Pharmaceutical Industry

The Indian pharmaceutical industry is witnessing a profound transformation, transitioning from a generics-oriented hub to an innovation-driven pharmaceutical economy, attributed to its prominent Contract Development and Manufacturing Organizations (CDMOs)[4].

Indian Govt initiatives

Government of India's focus on self-reliance of Active Pharmaceutical Ingredients (API) with production linked incentives has further increased the market size for digitalization. Recently, drug controller of India released draft Good Manufacturing Practices regulations for the industry. Enforcing these rules will trigger a huge demand for digitalization to make the operations efficient and sustainable.

Future trends in India's pharmaceutical industry encompass a transformative landscape marked by the adoption of cutting-edge technologies. According to a recent EY FICCI report, as there has been a growing consensus over providing new innovative therapies to patients, Indian pharmaceutical market is estimated to touch US$ 130 Billion in value by the end of 2030[2]. Meanwhile, the global market size of pharmaceutical products is estimated to cross over the US$ 1 Trillion mark in 2023[5].The pharmaceutical industry is undergoing significant transformations driven by key trends. Changes in the government and regulatory landscape are increasing the focus on quality assurance and control due to tightening policies and faster regulatory approvals.

Shifting industry dynamics are marked by a transition from "Make in India" to "Develop in India," globalization, rural market growth, and a shift towards collaboration among sectors. New go-to-market models are emerging, emphasizing the role of pharmacists, patient empowerment, and digital integration. In terms of talent and capabilities, there is a need to upgrade existing skills, adapt to emerging ones like digital and advanced analytics, and develop a talent pipeline by attracting talent from outside the industry. Investment in training and capacity building is vital to meet changing workforce expectations and skill requirements, as digitization becomes a cornerstone of transformation in the pharmaceutical sector.

Accelerated drug discovery is driven by AI and ML, significantly reducing time and costs. Personalized medicine, guided by data-driven insights, enhances therapeutic outcomes while minimizing side effects. Clinical trial optimization employs AI-driven algorithms, improving efficiency and cost-effectiveness. Supply chain transparency, ensured by blockchain technology, can safeguard drug authenticity. Telemedicine and digital health solutions broaden healthcare access, particularly in rural areas, with remote patient monitoring standardizing care. There is a lot to be excited about.

With the convergence of cutting-edge technologies, India's pharmaceutical industry is poised to maintain its position as a global leader while advancing patient care and improving public health both domestically and abroad.

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Trace Metals Analysis *via* ICP and ICP-MS

Accurate Data through Quality Sample Preparation

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In any laboratory carrying out trace elemental analysis, success in getting accurate and precise results largely depends upon the best quality sample preparation. This is the hardest job unless the lab is equipped with the right instruments for sample preparation, efficient and smart scientist going to use such equipment! If there is no confidence in your initial sample preparation stage, then there can be no confidence in the results from subsequent analyses. Good quality digestion of samples is therefore essential for achieving accurate results.

Today Modern analytical equipment gives an accurate analysis in a few minutes/seconds. The conventional sample preparation requires time, reagent consumptions and handling. Conventional sample preparation has become the bottle neck to higher productivity in the modern analytical laboratory. Typical flow diagram is given in Figure 1. However there are many steps to be considered along with Microwave Digestion System in Sample.

Let us discuss each step how we can optimize best conditions.

A. Ultra Pure Acid Supply – Ultrapure acids / Supra-pure acids are normally used in the process of samples digestion while doing trace level analysis. Using such acids is extremely important mainly to get blank signal count value extremely lower in Spectroscopy used compared to sample signals. As a thumb rule Sample Signal count should be at least three times higher than blank signal count!

There are many reputed suppliers who can supply ultrapure acids, and these are supplied with test certificates for the impurities present! But the issues encountered with such acids are,

a. Very expensive compared to AR grade acids (5-8 times expensive)

b. Normal practice is to buy bulk quantity as good discounts are available for bulk quantities. These are stored in high purity glass or polymer bottles! Where storage is in bottles there is risk of leaching of metals from the container material over a period. Also, if the bottle is left open by mistake there is a high possibility of cross contamination.

c. Considering acid consumption for 20-25 samples per day, one cannot consume whole bottle in a day once opened? So, is the validity of certificate not applicable subsequently once bottle in opened?

Alternately there are acid distillation systems available. These are quite convenient and economic! These are based on sub-boiling of acids technique, here acid distillation is carried out at much lower temperature than boiling point of acids, due to which majority of impurities are separated from bulk acids! Distilled acid purity is as good as ultrapure acids ! The advantages of using such systems are,

a) The purity of distilled acids obtained is very good!

b) One can distill quantity enough for the day's work! So, there is no question of cross contamination due to storage of the acids!

c) Automatic acid dozing pumps are also available to avoid manual handling of acids.

d) Typical ROI for the instrument cost, period is about 18-24 months! Subsequently one does not have to procure expensive acids at cost after this period!

Milestone srl Italy make the model duoPUR (sub boiling acids distillation system)

B. Automatic Acid Steam Cleaning System – While carrying out trace level elemental analysis there is a very high possibility of getting contamination from the glass wares used, spray-chambers and nebulizers in ICP systems. Therefore, good cleaning of these items is extremely important. Manual cleaning methods are laborious – time consuming, use high solvents used for cleaning purpose and are non-consistent. Automatic Systems uses Nitric Acid vapors very effectively and are most suitable especially for trace analysis. These systems are fully automatic, reliable and faster too. Acid consumption is very low as the same solvent gets recycled for next cleaning.

C. Reagent (acids) Handling – In an busy lab where there are very high sample loads, automatic reagent addition systems are best recommended . These systems have following advantages,

a) These are fully automatic acid / solvent dosing systems.

b) Eliminates risk of handling acids manually. Handles all types of acids.

c) Additions are automatic and accurate.

d) Rinsing and cleaning operations are automatic.

e) Faster operations.

f) These systems can also be used for preparing Calibration standards for ICP, ICP-MS.

D. Microwave Digester Vessels Handling: In case lab has very high load of samples to be digested

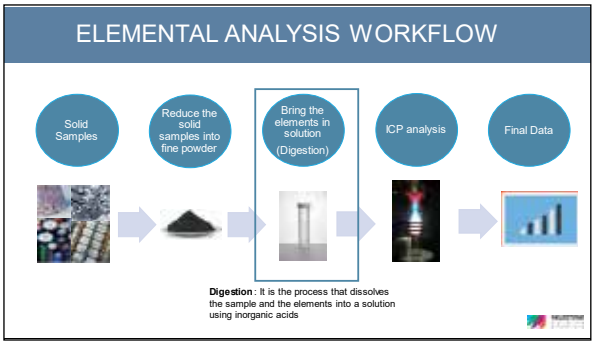

Figure 1

N.L.Deshpande holds M.Sc.Degree from Institute of Science, Mumbai. He worked with Associated Cement Companies for about 14 years when he got involved in R&D, Quality Control and Process Control activities on various products like catalysts and alumina products, cement etc. He had a long exposure in modern analytical techniques while working in the above areas. For the last 30 years he has been associated with I R Technology Services and has acquired vast knowledge on sophisticated analytical instruments and spectroscopic techniques like ICP, ICP-MS, XRF, etc.

Preparation workflow is presented in Figure 2.

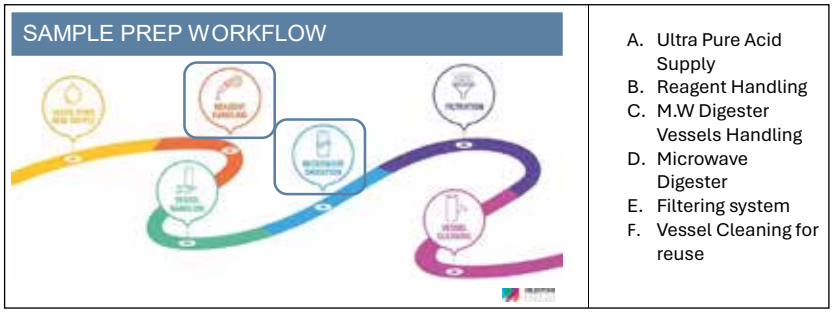

Figure 2

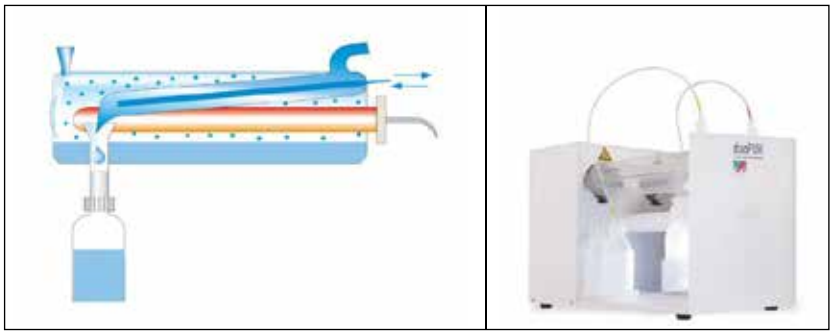

Figure 3

in Microwave Digesters, Automatic Capping Stations are helpful to have speed and consistency.

E. Microwave Digesters – Today this is well accepted technology in sample preparation for ICP, ICP-MS instruments. In this technique samples are placed in high purity Teflon vessels with closed lids with acids. Heating is done using controlled Microwaves and the temperature can be pre-set as per the requirements to digest different kinds of samples. Such systems have capabilities to increase solvent temperatures much more than normal boiling points on conventional Hot Plates! Typically, 180-200°C are temperatures used for Food type matrices and 250-270°C for tough matrices. There are different types of systems available like 'Multi-mode cavity' and 'SRC (Single Reaction Technology').

Advantages of Microwave Digesters are

a. **Good Quality Digestion:** This is most important for getting recoveries of all elements! Since digestion temperatures are much higher than hot plate conditions, digestion quality obtained is superior in Microwave Digesters

b. **High Throughput:** Different rotors are available which can hold multiple number of vessels in a single run (like 15 , 24 , 44 no's etc.)

c. **No loss of analytes during Digestion:** Since vessels are kept under closed conditions, there is no possibility of losing any analytes during digestion run. This is very important considering volatile elements like Hg, Pb, As, Sb etc.

d. **Less usage of acids:** Acid quantities used in Microwave Digesters are much lower as compared to conventional hot plate digestion methods.

e. The possibility of elimination of using acids like H_2SO_4, H_3PO_4, $HClO_4$ etc which are not recommended in spectroscopy techniques!

f. **Faster process of Digestion:** Due to higher temperatures used in Microwave digesters, digestion process is faster compared to conventional processes!

Figure 4
Automatic Cleaning system Model traceCLEAN (Milestone srl Italy)

Figure 5
Model easyFILL (Automatic Acid Dosing Station – Milestone srl Italy)

Figure 6
Model easyCAP (Automatic capping station -Milestone srl Italy)

'**SRC (Single Reaction Technology**') gives multiple advantages over conventional systems as below:

a) Much higher temperatures compared to conventional systems are possible (upto 280^{0}C). This is required for many difficult samples like refractories, some noble metal alloys, Zirconium materials etc.
b) This has a higher throughput system.
c) All matrices can be digested in a single run.
d) This uses single method for all matrices.
e) Very less acid quantity is required.
f) Cooling time is much lower as there is provision of water circulating chiller.

'Sample preparation is given little attention in the overall process for the analysis of trace metals, and for many sample types it turns out to be routine. Normally, scientists simply look at the detection limits for an ICP-OES or ICP-MS system and calculate back from a detection level or from interferences to determine the instrument of choice. Unfortunately, with highly organic sample types and the breadth of complexity increasing, the need for a good quality digestion process is more critical'.

A list of pre-analytical contributing factors that can affect the backend analysis includes **sample size, acid digestion volume, organic content, contamination, throughput, and post-digestion residual carbon content**. Each of these will play a role in the methods chosen for processing a sample. It is highly advisable that suitable techniques during sample preparation should be used (as mentioned above) before aspirating samples into ICP / ICP-MS analysers.

Figure 7 Multimode Cavity – Ethos UP system (Milestone srl Italy)

SRC Technology – UW3 system (Milestone srl Italy)

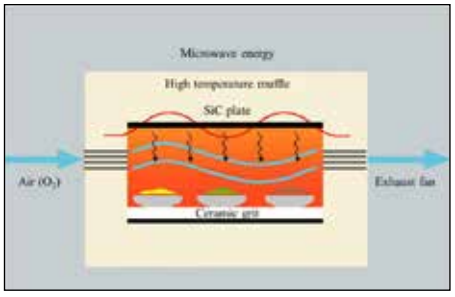

Figure 8 Model Pyro – Milestone srl Italy make

F. It is also important to mention here that many occasions, while carrying out trace elemental analysis ,it becomes essential to remove high organic matrix by burning it in furnace at higher temperatures (e.g 700-800°C) and then remaining residue is tested for the elements of interest. It improves the reliability of the analysis results. Best example can be polymer based materials where Titanium in small quantities is used as filler. One of the techniques to analyse Ti is, ash polymer based sample in the furnace and analyse residue obtained after ignition for Ti! For handling such ashing applications where organic contents are quite high, best efficient tool is High Temperature (1000°C) Microwave Furnace. This technique provides very fast ashing of the sample and also effectively handles dense gases produced during heating process.

Of course there are many applications which can be handle same ways like food, petroleum, catalysts etc.

Note: Analytical blank is a measure of all external sources of elemental contamination and is used to make a correction to the measured sample concentration. Achieving Lowest Analytical Blank may be considered as good as major success in Trace Analysis work.

'Special thanks to application support from the scientists of Milestone srl Italy, who educated and provided lots of scientific information time to time'.

UV-Vis Spectroscopy: A Gateway to Cutting-Edge Solutions

Yogesh Baldua
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UV-Vis Spectroscopy is a widely used analytical technique that studies the interaction of ultraviolet and visible light with molecules which will absorb UV-Vis radiation from 190 nm to 900 nm due to electronic transition. When molecules absorb light, it promotes an electron from a lower energy orbital to a high energy orbital.

UV and visible light is a small portion of electromagnetic radiation along with other radiations like X-rays, gamma rays, infrared, radio waves etc. The energy associated with electromagnetic radiation is defined using Planck's equation of E=hv where E is energy in Joules, h is Planck's constant and v frequency in seconds.

UV-Vis Spectrophotometry works on the principle of Beer - Lambert's law which states that absorbance (A) of a solution is directly proportional to the concentration of the absorbing species (C). Beer-Lambert's law can be written as A = €cl, where l is the path length and € is the molar absorptivity of the substance. Thus, for a fixed path length, UV-Vis spectroscopy can be used to determine the concentration of a target material in a solution. The wavelength of absorption peak can be correlated with the types of bonds in each molecule, even though many different compounds can yield very similar spectra. However, UV-Vis Spectroscopy can be extensively used as an excellent quantitative analysis tool. It is to be noted that the absorbance spectra can be affected by the nature of solvent, pH of the solution, temperature etc. The UV-Vis Spectrophotometer can measure Absorption, Transmission, or Reflection by samples. Thus, this technique has become an important tool in different segments of industry, academia, and research institutions.

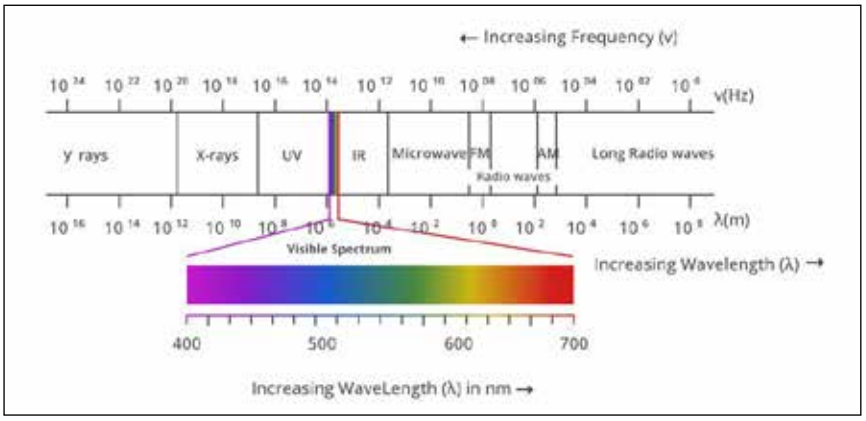
> ***The UV-Vis Spectrophotometer market in India is projected to reach an estimated market size of US$12 million, with approximately 2,200 units in demand by 2024. Further, UV-Vis spectrophotometer demand is expected to experience annual growth of 5% to 7% in the coming years. Indian market size of UV-Vis has been divided into two categories, imported brand and Indian brand.***

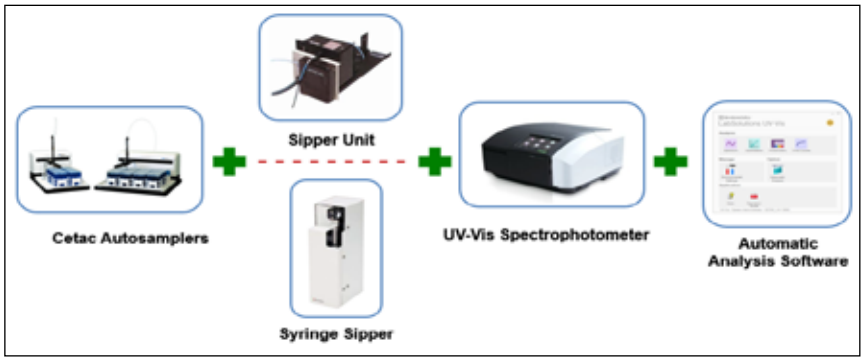
Over the last few years UV-Vis spectrophotometer has evolved as a versatile instrument to meet qualitative and quantitative analysis in various fields using advanced accessories and dedicated software. Right from standard double beam spectrophotometer having wavelength range from 190-900 nm to NIR range up to 3,000 nm, they are used to address variety of sample types, liquid, solid, film, glass and many more, in both transmission as well as reflection modes.

Apart from general application requirements in pharmaceutical, chemicals, food & breweries, academia and research institutions, solution-based UV-Vis demand is growing. Specialized hardware accessories like integrating sphere, absolute reflectance attachments,

film holder, temperature-controlled sample accessories, large and micro volume sample holders ease the analysis of versatile sample types. Also, software solution like colour measurement, temperature melting analysis, thin film studies, solar radiation calculation, ultraviolet protection factor etc. have added lot of value in complex UV analysis with respect to data generation and interpretation which is helping companies to comply with respective regulatory guidelines.

- Some of these key application solutions are covered here:
  - o Automation in UV spectroscopy to handle high throughput and cleaning validation samples in pharmaceuticals.
  - o Colour measurement in glass, pharma, food, and other industries
  - o Melting temperature analysis in biopharma and life science applications.
  - o UV-VIS-NIR analysis in anti-reflection coating.

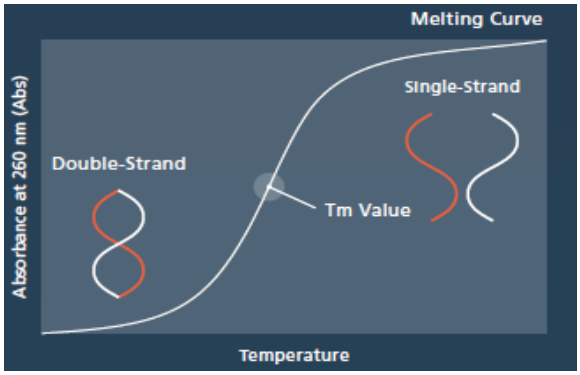




Compliance Based Automation for Pharmaceutical Industry

UV-Vis Spectroscopy is a widely used analytical technique in pharmaceutical industry and research. Routine analysis includes raw material testing as per pharmacopeial methods, dissolution testing, content uniformity, kinetic studies, cleaning validation etc. Addressing large sample loads, uncertainty in analysis and better compliance has always been challenges in pharmaceutical and chemical industries, especially when using manual UV-Vis spectrophotometer operation for application such as cleaning validation and routine QC testing to address large sample load. Now UV-Vis spectrophotometer can be connected to high throughput autosampler, sipper unit with rinse facility and dedicated software with compliance to address 100 or more samples. Automation will

Yogesh Baldua has completed is post-graduation from Devi Ahilya University, Indore and he is currently working in Toshvin Analytical Pvt. Ltd. as Dy. General Manager (Elemental & Spectroscopy) for pre-sale and post sales support for Shimadzu range of instruments. Yogesh has worked with many reputed analytical brands in various capacity in sales. With overall experience of 27 years he is involved in developing Shimadzu elemental and spectroscopy in India.



help companies to achieve better repeatability, compliance and can address high throughput sample analysis requirement by reducing manual sample handling and contamination issues.

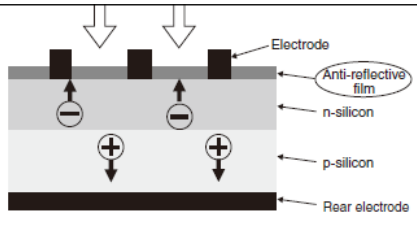
Colour Measurement

Colour is an important quality attribute of a product which has a direct impact on the consumer. Colour measurement is gaining lot of importance in many applications involving food, textiles, pharmaceuticals, herbal, nutraceuticals, glass, breweries etc. Colour testing is performed by either colour matching or colour measurement. Colour matching is not describing the colour qualities how it looks to human eyes but it is basic way to reproduce the developed colour.

Colour measurement is calculated in a numeric value using the spectral distribution of the illumination, the spectral reflectance of the object, and the colour-matching function of the eyes that are defined in JIS standards.

The colour measurements are performed by Illumination of spectral distributions and colour matching function values are stored in the colour measurement software to obtain colour measurement values when the spectral reflectance spectrum is measured. The XYZ tri-stimulus values are the basis of colour measurement. JIS Z 8722 'Methods of colour measurement - Reflecting and transmitting objects' calculates the XYZ tri-stimulus values.

Colour measurement can be carried out by use of colour space analysis using CIELAB numeric scale introduced in 1976 to distinguish between colour character which provides colour parameters in L, a, b values which is widely used. 'L': as 'lightness' and gives an indication of the 'depth' of colour observed in the sample, 'a:' used to measure red and green character with positive a-value having redder and more negative a-value more green character, 'b': define the blue/yellow character of a sample with positive b-values being more yellow, and negative b-values more blue.



Basic Structure of Silicon Solar Cell

Varible Angle Absolute Reflectance Attacl

Melting Temperature Analysis

Oligonucleotide therapeutics have been attracting attention in recent years to treat wide range of diseases. In developing and evaluating oligonucleotide therapeutics, it is important to understand thermal stability, which is a factor that governs structure and function. Melting temperature analysis serves an important role in checking the thermal stability and sequence of nucleic acids. In this analysis, heat is applied to the nucleic acids in double-strands. Then, the change in absorbance that occurs as the temperature increases and the strands dissociate into single strands is measured. The melting temperature is determined as the temperature where the mole fractions of single and double strands are equal.

This analysis can be performed using UV-Vis Spectrophotometer with temperature controlled multi-cell holder and melting temperature software. The steps involved checking of UV-Vis spectrum, annealing, measuring the melting curve, and analyzing data.

Annealing is a very complex process in melting temperature analysis. In manual mode, annealing temperature needs to be entered manually every time. However with automated software solution time-consuming annealing, correction (background wavelength and temperature blank correction), and melting temperature value calculation steps can be performed automatically. Annealing is a process of joining single stranded DNA or RNA by hydrogen bonds to form double stranded polynucleotides. There are many ways to denature the complementary strand and to remove any secondary structure than allow the strand to hybridize. Annealing occurs more efficiently when the temperature has been slowly increased after denaturation.

Since nucleic acids are available in

very less quantity and expensive, the semi microcells of 10 mm with minimum sample volume of 100 µL and 1 mm with minimum sample volume of 10 µL, are used with multi-temperature cell holder for high sensitivity measurements. New sealing methods are used which suppress the evaporation of samples by sealing the top side of the cell, enables reliable measurement of samples with high melting temperatures.

Measurement of Anti-reflection Coating.

Anti-reflection coatings are used in a wide variety of products, such as lenses, eyewear, various displays, automotive windshields, solar cells, and optical communication devices to improve the visibility by reducing incident light. It is a key factor that determines product quality hence it is important to measure the transmittance and reflectance more accurately.

Anti-Reflective Film for Solar Cells

As the population continues to surge, there is a heightened emphasis on exploring new sustainable energy sources to meet the increasing demand. Renewable energy sources should prioritize environmental friendliness, minimal CO_2 emissions, abundance, and accessibility for widespread use. From this perspective, solar power has got major attention in current years. Solar films and solar cells require testing using spectrophotometer in NIR region with reflectance accessories. Specially designed solar cells are used to convert solar energy into electrical energy. The challenge is to collect, convert, store, and distribute solar energy. It should also be efficient and cost effective.

To increase the amount of sunlight reaching the solar cell, antireflective films are used. It suppresses the reflection of incidence light from the surface of the solar cell, thereby preventing the loss of light energy, increasing absorption, and improve power conversion efficiency. Therefore, measuring the reflectance of anti-reflective film is an effective means of evaluating the performance. This can be measured by absolute reflectance attachment accessory.

Solar panels incorporate glass panels for the protection of the solar cells, resulting in their relatively larger dimensions. UV-Vis-NIR with large sample holders can be used to check the transmittance properties of such wider samples.

UV-Vis Spectroscopy Market Demand in India

The UV-Vis Spectrophotometer market is projected to reach an estimated market size of US$12 million, with approximately 2,200 units in demand by 2024. Further, UV-Vis spectrophotometer demand is expected to experience annual growth of 5% to 7% in the coming years. Indian market size of UV-Vis has been divided into two categories, imported brand and Indian brand. Some of the reputed brands are listed in the table below.

As the new emerging application demand grows the testing demand for UV-Vis spectroscopy analysis will also increase. To substantiate this, the Oligonucleotide market is growing at 15% CAGR. Similarly anti reflection coating demand is growing so high-end UV with specialized accessories can be considered for testing for routine QC check. Apart from above, UV-Vis Spectrometry is also used for dedicated applications like water testing, colour matching and nanodrop analysis, which are not considered part of mainstream UV-Visible spectroscopy market in this article.

Imported Brands	Domestic Brands
Shimadzu Corporation	Labindia
Agilent Technologies	Elico
Thermo Scientific	Motras Scientific
PerkinElmer	Systronics
Jasco	
Mettler Toledo	

Due to stringent regulatory requirements, UV-Vis spectroscopy major markets like pharma, life science, chemical, food and breweries etc., prefer precise, sensitive, and reliable instruments which fulfill specialized applications demand. Compliance with 21 CFR Part 11 guidelines for UV-Vis spectrophotometers is an indispensable requirement within the pharmaceutical industry. The need for such compliance is also growing within other industries engaged in product exports. Today UV-Vis spectroscopy technique users are carefully evaluating and selecting brand, specifications and accessories that can right fit to their requirements and at the same time analytical instrument manufacturer's are also working towards continuous improvement of specifications and robust software solutions so as to further widen the application scope of UV-Vis spectroscopy.

Conclusion

The UV-Vis Spectrophotometer is one of the most widely used analytical instruments across industry, academia, and research activities. It can be effectively used for routine analysis and more complex applications. Different accessories are available catering to various applications. Coupled with very powerful software, it can help analytical chemists to carry out various applications with less effort and higher accuracy.

MALDI-TOF Technology Transforming Analytical and Life Science Instrumentation in India

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In the realm of analytical and life science instrumentation, Mass Spectrometry (MS) has emerged as a cornerstone technology for researchers and scientists worldwide with a market value up to 6 billion USD/Year. Among the various MS techniques, Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry (MALDI-TOF MS) has been a game-changer since its inception. Over the past few decades, this technology has undergone remarkable advancements, reshaping the landscape of scientific research, diagnostics, and drug discovery. In this article, we delve into the fundamentals of MALDI-TOF technology, its historical context, its current state, and future in India.

Understanding MALDI-TOF Technology

The Basics of MALDI-TOF MS

MALDI-TOF MS is a powerful analytical technique used for the determination of molecular masses of a variety of compounds such as proteins, peptides, nucleic acids, metabolites and lipids, polymers etc. MALDI is one of the two soft ionization techniques, the other being electrospray ionization, that allows ionization of previously difficult-to-ionize mid and large sized biomolecules. The lower energy (softness) of the MALDI ionization mechanism produces far less fragmentation than using traditional method such as electron ionization commonly used in chromatography-mass spectrometry (GC-MS), thus allowing the preservation of these labile biomolecules crucial in their downstream manipulation within the mass spectrometry regime.

The key components of a MALDI-TOF MS instrument includes.

Matrix: An organic compound mixed, and co-crystalized with the sample, which assists in the ionization process.

Laser: A high repetition-rate UV laser that irradiates a matrix-sample crystals, causing it to become ionized.

TOF Analyzer: A Time-of-Flight (TOF) mass analyzer measures the flight time of ions to determine their mass-to-charge ratio. It provides mass spectra that help identify and quantify the ions present in the sample.

Detector: A detector that records the abundance of ions at their corresponding the time-of-flight (and ultimately their mass).

At its core, MALDI-TOF operates on the principle of ionization and mass separation. The combination of MALDI and TOF is the most ideal use of ions because they are both pulsed techniques; the ions are utilized most efficiently because they are generated (ionized by MALDI) only when the TOF analyzer is ready to measure their masses. Here's a simplified breakdown of how it works:

Sample Preparation: The sample of interest, typically a mixture of molecules, is mixed with a matrix material. The matrix is chosen based on the ionization affinity with a targeted compound class such that large molecules like intact proteins is usually paired with Sinapinic acid (SA), while peptides are paired with Cyano-4-hydroxycinnamic acid (CHCA), and small molecules paired with Dihydroxybenzoic acid (DHB). These matrix-sample mixtures are then spotted on MALDI target plate and allowed to dry at atmospheric condition (Fig.1). This matrix absorbs laser energy and helps facilitate the ionization of analyte molecules.

Laser Irradiation: A pulsed laser beam is directed onto the crystallized matrix-analyte mixture, whereby the matrix absorbed the radiation, causing the matrix-sample crystal structure to destabilize

into a gaseous plume, as energy is transfer to the analyte molecules. This process leads to the ionization of the analyte molecules.

Ion Extraction: The ionized analyte molecules are accelerated by an electric field and then released into the Time-of-Flight (TOF) analyzer.

Mass Separation: In the TOF analyzer, ions travel through a flight tube and are separated based on their mass-to-charge ratio (*m/z*). Lighter ions reach the detector faster than heavier ones (in microsecond time scale).

Detection: The ions are detected at the end of the flight tube, creating a mass spectrum. This spectrum provides information about the mass and abundance of the ions, allowing for the identification and quantification of the analyte molecules.

Historical Evolution

The origins of MALDI-TOF MS can be traced back to the 1980s when Dr. Franz Hillenkamp and Dr. Michael developed the technique and Mr. Koichi Tanaka first demonstrated the of ionization of proteins using MALDI. Mr. Tanaka was awarded the Nobel Prize in Chemistry in 2002 for his groundbreaking work. Since then, MALDI-TOF MS has continually evolved, with improvements in resolution, sensitivity, and speed.

MALDI-TOF Applications

The versatility of MALDI-TOF technology has led to its widespread adoption across various scientific disciplines and industries. Some key applications include:

Proteomics

MALDI-TOF mass spectrometry has become indispensable in the field of proteomics. 2D Gel MALDI-TOF and LC-MALDI-TOF are vital tools in proteomics research. 2D Gel MALDI-TOF combines two-dimensional gel electrophoresis with mass spectrometry to analyze protein samples, enabling the identification of proteins based on mass and isoelectric point. It is widely used for comparative protein expression analysis and post-translational modification studies, aiding in biomarker discovery.LC-MALDI-TOF integrates liquid chromatography with mass spectrometry, enhancing the separation and identification of complex protein mixtures. This technique is indispensable for in-depth proteome profiling, quantification, and characterization, making it valuable in various biological and clinical applications, including disease biomarker research and drug development.

Microbiology

In clinical microbiology, MALDI-TOF has revolutionized the identification of microorganisms. By analyzing microbial protein mass spectra, laboratories can rapidly (minutes compared to hours with conventional methods) and accurately identify bacteria, fungi, and other pathogens. In addition, the marked advantage of MALDI-TOF-based microbial identification is in the analysis of sepsis sample directly from the hemoculture bottle. This has greatly improved the diagnosis and treatment of infectious diseases.

Pharmaceutical Industry

MALDI-TOF mass spectrometry plays an important role in the biopharmaceutical industry. It is instrumental in Glycomics and Protein characterization as analysis of intact, reduced and subunit proteins, glycoproteins, peptide mapping and oligonucleotides. For proteins, it aids in characterizing and verifying the integrity of

Mr.Venkatesh has a decade of extensive experience in mass spectrometry and has a master's degree in biotechnology coupled with a strong foundation in analytical software. His expertise covers protein characterization (Intact/ PMF/PTM), peptides, metabolomics, and small molecule complexes. He was Associate Scientist at Syngene International, Product Specialist-Mass spec at Inkarp instruments Pvt Ltd, , and is now an Application Specialist in the Bruker Mass Spec division. He has excelled in developing and applying advanced MS methodologies, utilizing techniques ranging from sample preparation and separation to various MS instruments, including TIMS, MALDI, QTOF, ION TRAP, and ORBITRAP.

therapeutic monoclonal antibodies, ensuring product quality and consistency. In glycoprotein analysis, it helps decipher glycan structures critical for drug efficacy and safety. Peptide mapping enables the identification of post translational modifications (PTMs) and impurities as part of regulatory documentation. Oligonucleotide analysis ensures the purity and sequence of nucleic acid-based drugs. MALDI-TOF's speed, accuracy, and sensitivity make it an indispensable tool for quality control, research, and development in biopharma, ensuring the safety and efficacy of biotherapeutics.

Lipidomics

Thin Layer Chromatography-MALDI TOF (TLC-MALDI TOF) is a valuable technique in Lipidomics, the study of lipid molecules in biological systems. It allows for the separation and identification of lipids on a thin chromatographic plate, followed by precise mass analysis using MALDI-TOF mass spectrometry. This approach is essential for profiling lipid classes, identifying specific lipid species, and studying their variations in cells, tissues, or biofluids. TLC-MALDI TOF is crucial for understanding lipid metabolism, membrane structure, and their roles in various biological processes, including diseases like cancer and metabolic disorders, making it an indispensable tool in Lipidomics research.

Imaging & Cancer Biology

MALDI Imaging allows for precise mapping of biomolecules within tissues, offering insights into disease mechanisms and drug distribution. In drug discovery, it accelerates the analysis of drug candidates and their interactions within biological samples, expediting the development process. Recent advancements include improved spatial resolution and multimodal imaging, allowing for simultaneous analysis of various molecules. Research institutes are increasingly using MALDI-TOF Imaging to study complex biological systems. Its ability to provide spatially resolved molecular information is a game-changer in understanding diseases, drug response, and tissue function, propelling advancements in biomedicine and pharmaceuticals.

Cancer is a multifaceted disease, as tumors are characterized by their heterogeneity, plasticity, and intricate interactions of cancer and stromal cells within the microenvironment. By interrogating the distribution of metabolites, lipids, peptides, proteins, and glycans within tissues, MALDI-IMS can give researchers a profound understanding of cancer biology. This spatially resolved data empowers researchers to create new diagnostic and prognostic tools and targeted treatment strategies. Personalized medicine becomes attainable, as therapy can be tailored to the individual patient's unique cancer profile within the larger clinical context, potentially transforming the prognosis for historically lethal cancers.

The integration of MALDI-IMS with other analytical techniques, such as lipidomics, metabolomics, proteomics, genomics, and transcriptomics becomes crucial by amplifying its impact. Combined data analysis facilitates peak annotation, biomarker discovery, and a deeper understanding of biological and biochemical processes. These insights contribute to unraveling the complexities of cancer and identifying novel therapeutic targets, revolutionizing drug development in the pharmaceutical and biopharmaceutical sectors.

Despite its successes, MALDI-IMS faces challenges, such as quantification and the detection of low-abundance proteins within the complex proteome on heterogenous tissues. Breakthroughs like the HiPLEX method, utilizing antibody probes and mass tagging for protein detection, provide increased selectivity and sensitivity. The ultimate goal of achieving "proteomics on tissue" remains a tantalizing prospect, actively pursued by researchers in the field.

Industrial

Some other applications including polymer analysis, leather, ocean samples, and nanoparticle characterization, with recent advancements enhancing its capabilities.

In polymer analysis, MALDI-TOF MS is employed for molecular weight determination, distribution, and structural characterization. Recent developments in software as Polytools to do polydispersity estimation, impurities, and quantification to improve accuracy, enabling precise control over polymer synthesis and formulation, vital in industries like plastics and materials. In leather processing to identifiy protein content, tanning agents, and contaminants. For nanoparticle analysis, this technology offers size, composition, and surface information crucial in nanotechnology and material science. Cutting-edge developments include tandem MS techniques for improved nanoparticle characterization.

In all these applications, MALDI-TOF MS's sensitivity, speed, and versatility, combined with recent technological enhancements, continue to drive advances in research, quality

Fig. 1: Spotting on MALDI Target plate.

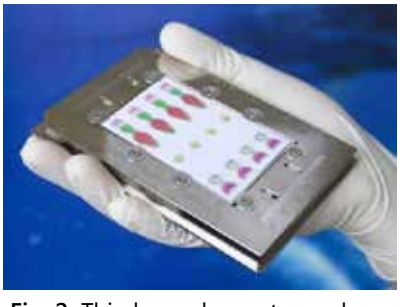

Fig. 2: Thin layer chromatography MALDI TOF Target plate

control, and product development across diverse industries, fostering innovation and problem-solving in these areas.

The MALDI-TOF Impact in India

India, with its burgeoning scientific community and healthcare sector, has embraced MALDI-TOF technology with enthusiasm. India currently boasts a mass spectrometry market of up to 34 million USD with 3 to 4 million in MALDI-TOF alone. The MALDI-TOF technology has found applications in various domains within the country:

Clinical Diagnostics

In Indian hospitals and diagnostic laboratories, MALDI-TOF has become a game-changer in the rapid identification of infectious agents. The technology has reduced the time required for diagnosing bacterial and fungal infections, facilitating timely treatment decisions, and improving patient outcomes.

Biomedical Research

Indian researchers have harnessed the power of MALDI-TOF for cutting-edge biomedical research. From proteomics studies aimed at understanding diseases like cancer to microbiome research exploring gut health, MALDI-TOF has enabled India's scientific community to make significant contributions to global knowledge.

Pharmaceutical Industry

India's pharmaceutical industry, renowned for its generic drug manufacturing capabilities, relies on advanced analytical techniques like MALDI-TOF for quality control, drug development and stability studies. This has helped Indian pharmaceutical companies meet international standards and expand their global reach.

Agriculture and Food Science

MALDI-TOF is also being applied in agriculture and food science in India. Researchers are using it to analyze food contaminants, identify pathogens in agricultural products, and study the composition of edible oils (TLC-MALDI).

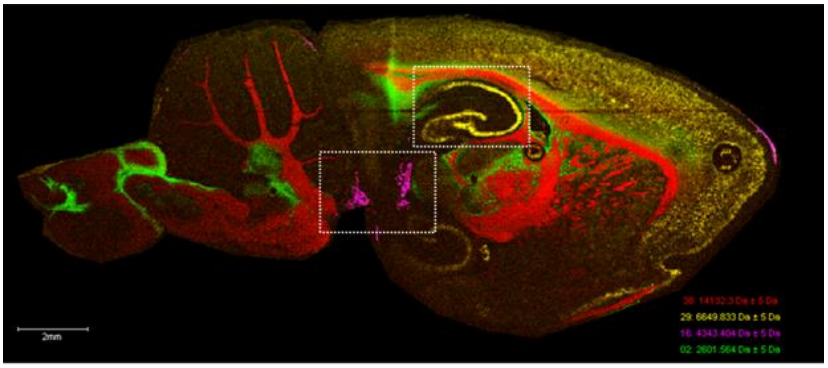

Fig. 3: Two highly localized ion distributions show delicate structures such as the hippocampal pyramid cell layer (b) and the ependyma Proteins in sagittal rat brain section, 150.000 pixels.

Future Perspectives

As we look to the future, the MALDI-TOF technology in India is poised for significant growth and innovation. Several key developments and trends are likely to shape its trajectory:

Advancements in Instrumentation

The next generation of MALDI-TOF instruments will feature improved sensitivity, resolution, and higher throughput. These advancements will open new possibilities for research and diagnostics, enabling the analysis of even more complex samples and large cohort studies.

Clinical Integration

The integration of MALDI-TOF technology into clinical practice is expected to deepen. Its applications will expand beyond microbial identification to include the rapid profiling of patient biomarkers, aiding in personalized medicine and disease monitoring. Recent years have witnessed significant advancements in MALDI-IMS technology. Spatial resolution has improved to resolutions as low as 5 microns, enabling the visualization of individual cells. Enhanced speed, with up to 50 positions per second, facilitates high-throughput studies essential for large cohort clinical research. Improved mass spectrometry sensitivity, optimized samples processing, ionization, and innovations like post-ionization MALDI-2 further extend the depth of the data collected. Accompanying software suites offer refined, user-friendly analytics, including univariate and multivariate analyses.

Automation and High-Throughput Screening

Automation will play a crucial role in making MALDI-TOF technology more accessible and efficient. High-throughput screening capabilities will allow for the rapid analysis of large sample sets, accelerating research, diagnostics, and Industrial trials.

Multimodal Approaches

Researchers will increasingly combine MALDI-TOF with other analytical techniques, such as liquid chromatography, thin layer chromatography and 2D gel electrophoresis. This multimodal approach will provide a more comprehensive understanding of complex biological systems.

Data Analytics and AI

The sheer volume of data generated by MALDI-TOF experiments will necessitate advanced data analytics and machine learning techniques. Artificial intelligence (AI) will assist in data interpretation, pattern recognition, and the discovery of novel insights.

Cost Reduction

As technology matures and competition grows in the analytical instrument market we can expect a gradual change in the overall cost of MALDI-TOF instruments based on application oriented solutions from routine to high end research. This will make the technology more accessible to smaller research laboratories and clinics.

Market Dynamics in India

India's analytical and life science instrumentation market is dynamic and rapidly evolving and in future MALDI-TOF market will reach up to 8 million USD. Several factors are influencing the market dynamics:

Government Initiatives

The Indian government has been actively promoting research and innovation in science and technology. The aim is to position India as a hub for innovation, healthcare, and pharmaceuticals.

1.1 **National Biopharma Mission (NBM)**: Launched as part of the 'Make in India' campaign, NBM seeks to accelerate biopharmaceutical research and development. It offers funding, infrastructure support, and mentorship to startups and innovators in the life sciences sector.

1.2 **Biotechnology Industry Research Assistance Council (BIRAC)**: BIRAC, a government body, supports research and innovation in biotechnology by providing grants, incubation facilities, and partnerships with private sector companies.

1.3 **Atal Innovation Mission (AIM)**: AIM promotes entrepreneurship and innovation across various sectors, including life sciences. It provides funding, mentorship, and resources to foster a culture of innovation.

1.4 **DBT (Department of Biotechnology) and DST (Department of Science and Technology):** These government departments regularly allocate substantial funds for research projects, human resource development, and infrastructure enhancement in life sciences.

1.5 **COVID-19 Response:** During the pandemic, the government increased funding for vaccine development, diagnostics, and treatment research, showcasing its commitment to public health.

Growing Healthcare Sector

India's growing population and increasing healthcare needs are driving investments in diagnostic and research instrumentation. The demand for analytical instruments, technologies like MALDI-TOF is expected to continue rising.

Academic and Research Institutions

Indian universities and research institutions are expanding their capabilities in life sciences and biotechnology with multiple government and private fundings to establish new facilities with high end analytical equipment. This has led to a higher demand for advanced analytical instruments, including MALDI-TOF, for research and education.

Global Collaborations

Indian researchers and institutions are actively collaborating with international partners. This exchange of knowledge and expertise has accelerated the adoption of cutting-edge technologies, including MALDI-TOF for different application as Tissue Imaging, High throughput MALDI screening etc.

Market Competition

The analytical and life science instrumentation market in India is becoming increasingly competitive with global access. Both domestic and international companies are vying for market share, leading to innovation and cost-effective solutions.

Regulatory Environment

Stringent regulatory requirements in healthcare and pharmaceuticals are driving the need for advanced analytical instrumentation for better accuracy and reproducible results for different regulatory bodies like FDA (U.S. Food and Drug administration). Compliance with international standards is essential for market success.

Conclusion

Matrix-Assisted Laser Desorption/ Ionization Time-of-Flight (MALDI-TOF) technology has emerged as a transformative force in analytical and life science instrumentation, with far-reaching implications for research, diagnostics, and healthcare in India. Its applications span diverse fields, from clinical microbiology to drug discovery and environmental monitoring.

Looking ahead, the future of MALDI-TOF in India is bright, marked by advancements in instrumentation, greater clinical integration, automation, and AI-driven data analysis. These developments will further empower researchers, clinicians, and industries to harness the full potential of this technology.

The changing market dynamics in India, driven by government initiatives, a burgeoning healthcare sector, and increased research collaborations, will continue to shape the landscape of analytical and life science instrumentation. As competition intensifies, innovation and cost reduction will be key drivers of growth, ensuring that advanced technologies like MALDI-TOF reach a wider audience and contribute to scientific progress and improved healthcare outcomes across the nation.

Evolution of FTIR Platform and its Market Trend in India

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India has emerged as the fastest-growing major economy in the world and is expected to be one of the top three economic powers in the world over the next 10-15 years. India is primarily a domestic demand-driven economy, with local consumption contributing to 70% of the economic activity. To improve economy several initiatives like PLI (Production linked incentive) schemes were launched into various sectors, along with focusing on renewable sources to generate energy and to achieve 40 % of its energy from non-fossil sources by 2030.[1] These initiatives are bound to drive the growth and demand of analytical instrumentation across industries to cater to the need of quality products and meet the various regulations. The Indian analytical instrument market size reached a value of around USD 3.4 billion in 2022, driven by the growing demand of quality control and assurance, increasing research and development, and technological advances. The market is further expected to grow at a CAGR of 11% during the forecast period of 2023-2031, likely to attain a market value of around USD 8.6 billion by 2031.[2]

Fourier Transform Infrared Spectroscopy (FTIR): Introduction

FTIR spectroscopy has emerged in recent years as the analytical method of choice in an enormous variety of applications. What brought about this revolution?

The clearest advantage is that no specific reagents are required. Automated, repetitive analyses can therefore be carried out at very low-cost. The appeal of these factors has spurred the development of a new generation of analytical FTIR spectrometers that combine high acquisition speed with superb spectral sensitivity. Powerful chemometric algorithms and software packages have emerged in parallel with the new hardware, and new applications emerge continually.

We measure infrared spectra to answer 3 questions about samples[3].

A) What molecules are present in this sample?

   The peak positions in an infrared spectrum correlate with molecular structure, and the peak positions of known molecules derived from these spectra can be used to identify the molecules in an unknown sample.

B) Are these two samples the same?

   When performing a spectral comparison or identity test we compare the unknown spectrum to a reference spectrum and noting how well the peak positions, heights, and widths in the two spectra match. Comparing spectra to each is easier than interpreting an unknown spectrum, and modern software capability makes it easier & robust.

C) What are the concentrations of molecules in this sample?

   To do this one must measure the spectra of samples of known concentration, and then use Beer's Law to prepare a calibration line relating absorbance to concentration. Once the calibration has been generated and validated it can be used to determine the concentration of molecules in unknown samples.

Fourier Transform Infrared Spectroscopy (FTIR) Market, By Type

Classification of FTIR in market is based on its application and usage type, the market is segmented into Benchtop FTIR Spectrometers, Portable FTIR Spectrometers, and Others.

The most commonly used FTIR's are Benchtop FTIR spectrometers that are quick and dependable tools for material identification and quantification. They are typically compact and rugged, making them

appropriate for laboratory and process applications. Some of the routinely found benchtop FTIR are PerkinElmer-Spectrum-2 (Figure 1) , Bruker Alpha II, Shimadzu IRSpirit, Thermo-Nicolet iS20, Agilent Cary 630, Jasco FTIR-4X. All these are dedicated, compact Mid-IR benchtop FTIR that are extensively used for chemical analysis, quality control of samples along with identification and quantification of samples.

Then we have next classification of FTIR that are benchtop & research grade which usually operate not only in Mid IR but also in Far-IR & Near-IR range and capable of measuring both solid, liquid and gaseous sample and can be integrated with various 3rd party accessories (Specac, Pike, Harrick's) meant for doing transmission, specular/diffuse reflectance, remote measurement, low/high temperature measurement along with integration with microscopy to study high resolution chemical imaging of samples.

The 3rd classification as Others are usually FTIRs that are integrated as Analyzers and are meant for specific & dedicated applications with customized software solutions to generate data either meeting specific regulatory guidelines or methods. Most common application involves gas monitoring, batch sampling, in-line process monitoring, chemical reaction monitoring, emission testing & proximate analysis in food matrices.

Fig. 1: Typical portable Spectrum Two FTIR with ATR from PerkinElmer.

Fourier Transform Infrared Spectroscopy (FTIR) Market, By Application

Food and packaging, gas analysis, environmental analysis, life science, research, oil and gas analysis, pharmaceuticals, and forensics are just a few of the applications for FTIR spectroscopy. Figure 2 shows the usage of FTIR across various market segment for India. The increase in FTIR spectroscopy applications is a key factor driving the growth of the global Fourier Transform Infrared Spectroscopy (FTIR) Market. Rapid technological advancements in FTIR spectroscopy have resulted in increased R&D activities in the field by several biotechnology and pharmaceutical companies.

Furthermore, the implementation of strict packaging and food labeling regulations has accelerated the adoption of FTIR spectroscopy instruments in the food industry. Increased use of FTIR spectroscopy in the life science and pharmaceutical industries propels market growth during the forecast period. In the drug development process, FTIR spectroscopy is used to screen intermediates and raw materials. It is also used in quality control processes and formulation preparation.

FTIR for Polymer/Chemical Industry

Infrared spectroscopy is ideally suited to qualitative analysis of polymer starting materials and finished products as well as to quantification of components in polymer mixtures and to analysis of in-process samples. IR spectroscopy is dependable, fast and cost-effective. Polymer samples can be identified using IR spectra analysis that would require a standalone FTIR along with ATR accessory and a polymer resource library pack that can help identify the polymer based on reference spectra database. Figure 3 shows the IR spectra of several common polymers: polyethylene (PE), polypropylene (PP), polystyrene (PS), and polytetrafluoroethylene

- ***Estimated market potential for FTIR in INDIA is 34 million US$ and growing at CAGR of 5.3 %.***
- ***Yearly ~ 900 units of FTIR (Mid-IR & Standalone) are sold annually.***
- ***PerkinElmer, Shimadzu, Bruker, Thermo-Fisher, Agilent, Jasco are leading global FTIR brands that sells FTIR in INDIA.***

(PTFE), measured using the PerkinElmer Spectrum Two FTIR with UATR sampling accessory, as shown in Figure 1. The clear differences between the spectra allow a ready discrimination between the materials by visual inspection. Additional interpretation of the spectra can yield information about the structure-for example, looking at the C–H stretch region around 2950 cm-1, differences can be seen between PE and PP due to the differing ratios of CH_2 and CH_3 groups. PS has bands above 3000 cm^{-1}, indicating the presence of aromatic groups. PTFE has no C–H groups at all, so the very weak bands present must be due to impurities or surface contamination. Once spectral data has been collected, PerkinElmer's Spectrum 10™ software can carry out a wide range of spectral Analyses. The available options in the Polymer ID analyzer include:

- Search – for identification of samples comprising a single polymer where the identity of the sample is unknown.
- MultiSearch™ - for estimation of polymer mixtures where the components' spectra are available.
- Compare – for verifying the materials quality by comparing its spectrum against those of samples of known quality or composition.Quant™ - for

determining the composition of mixtures using a pre-developed calibration to calculate the component concentrations from the spectra.

- Verify – similar to compare, but more effective when it is necessary to take into account within-batch and/or between-batch variability when confirming the materials spectrum against those of known identity/quality.

FTIR spectroscopy is a powerful tool for polymer analysis, and a range of sampling methods are available with varying degrees of sample compatibility and time requirements. The Spectrum Two FTIR spectrometer with the UATR sampling accessory and the Polymers QA/QC FTIR Resource Pack is the ideal system for routine analysis and identification of polymer samples. With ATR sampling, good-quality spectra were obtained from industrial samples in seconds, and the materials were identified by searching against the library supplied with the system.

FTIR for Petrochemical Industry

Reducing our dependence on fossil fuels and our reliance on oil and petroleum supplies are worldwide issues. Many see the increasing use of biodiesel fuel as a key initiative to meet these global needs. However, the move to include proportions of biodiesel in everyday fuel has created a host of unresolved issues for both engine manufacturers and diesel consumers. Uppermost among these are questions concerning the concentration of the biofuel (Fatty Acid, Methyl Ester – FAME) and its quality.

FTIR-ATR technique can be used to address the FAME concentration measurements. A key advantage of using an ATR sampling method is speed and simplicity. This can really help in laboratories where multiple analyses are routinely performed. The choice of either Beer's Law or chemometrics will be determined by either load of high sample or preference for high accuracy. The Beer's Law approach benefits from being simpler but is only recommended for situations where there is a low throughput of samples and the accuracy requirements are not high. The chemometrics approach has the advantage of being more robust

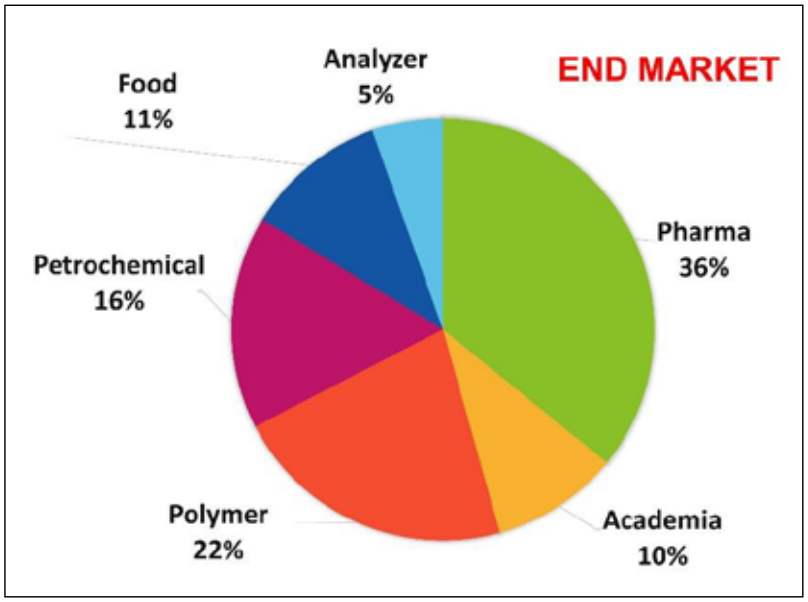

Fig. 2: FTIR instrumentation market share for various industry segment.

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with respect to known constituents in the blend, better handling of interferences, and reduced effect from noise contributions. Overall, PCR offers far higher confidence in the quantitative prediction than is found using the Beer's Law methods.

FTIR for Food Industry

Trans-fats are mono- or polyunsaturated fats in which one or more of the double bonds is in a trans configuration. Trans-fats are present in small concentrations (2-5% of total fat) in milk and meat products from ruminants such as cattle and sheep, but otherwise are found only in processed, partially hydrogenated fats such as some vegetable shortenings and margarines. Consumption of trans-fats has been shown to increase the risk of heart disease, and there is increasing pressure on food manufacturers both to reduce their use of synthetic trans-fats and to label clearly the trans-fat content. Regulators in some countries (such as Switzerland, Denmark and Austria) have imposed strict limits on the amount of trans-fat that may be present in food ingredients, while in the U.S., Canada, much of South America, South Korea, Taiwan and Hong Kong labelling of the trans-fat content of foods is mandatory. These requirements have led to a need for a rapid, straightforward analytical method to measure the trans-fat levels in fats and oils. Gas chromatographic methods provide adequate sensitivity, but generally require a time-consuming transesterification step in sample preparation to produce fatty acid methyl esters (FAMEs) suitable for analysis.

Because of the distinctive molecular structure of trans-fats, the infrared spectrum contains a band that is not present in the spectra of other types of fats and oils. This feature has been used by the American Oil Chemists' Society (AOCS) to develop a standard test method, for trans-fats in edible oils and fats by FTIR with attenuated total reflectance (ATR) sampling. The analytical method is based around an ATR measurement. A thermostated ATR accessory is used to guarantee that the sample is liquefied and ensures reproducibility.

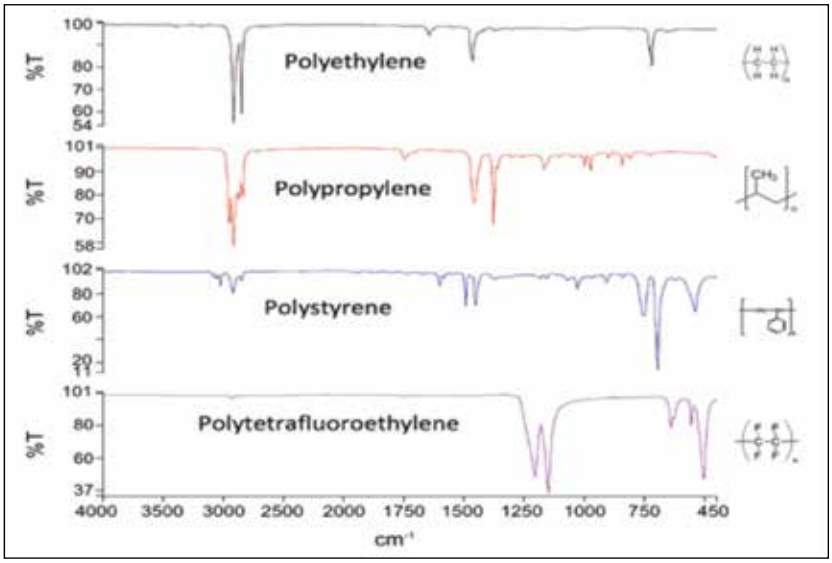

Fig. 3: FTIR spectra for commonly found polymers.

FTIR for Glass Industry

Emissivity is a key property in determining the energy saving ability of glazing. In the context of European Standardization with the introduction of CE mark and methods for the evaluation of conformity of products there is an urgent need to improve and standardize measurement methods pertaining to emissivity. FTIR along with IR specular reflection accessory can provide a complete solution for state-of-the-art measurement of the emissivity of coated glazing products according to international standards. The unique feature of the accessory is that it enables measurements on large tempered glass panes along with relatively small samples (as small as 5 mm) that are generally difficult to align, can be measured with this accessory. The usable wavelength range of the accessory is that of the FTIR configuration equipped with a KBr or CsI beam splitter. The accessory is designed to measure direct reflectance of specular samples at an angle of incidence of 6 degrees. The accessory is equipped with a 3-point sample support for maximum stability and accuracy. The accessory is accompanied by a set of five gold coated reference mirrors, of which one mirror is the primary standard that is used only to check and recalibrate the four other mirrors that are the so-called working standards. Customized inbuilt method helps get result for emissivity values for glass panes as per EN673.

FTIR for Pharmaceutical Industry

FTIR serves as a non-destructive, highly sensitive, specific and robust analytical technique by which almost any solid, liquid or gas sample can be analyzed with little or no sample preparation procedure without using any expensive, toxic solvents and reagents, so its economical as well as environment-friendly technique. A busy quality control lab needs fast, accurate results to analyze drug batches before release. Researchers look at batch-to-batch variations, identify foreign particulates, and assess chemical make-up to resolve issues or address complaints. During product development, R&D scientists aim to control and

Fig. 4: PerkinElmer Spectrum-3 with the EGA 4000 accessory.

optimize dissolution or distribution of materials through refinement and adjustment of formulations and processes. Identification of foreign particulates is critically important to pharmaceutical labs as well. Scientists use FTIR microscopy to identify and distinguish between non-proteinaceous and proteinaceous particles. FTIR Microscope offers a unique solution for the identification of foreign particulates in parenteral, biologics, and ophthalmic solutions. The system's ability to produce measurements in transmission, reflection, and attenuated total reflection modes is particularly valuable in pharmaceutical research which is a heavily regulated industry around the world. As regional regulations and sample types differ, the flexibility to follow the entire pharmaceutical workflow with one system, regardless of regulations or sample types, provides key efficiencies in the lab.

Latest Innovations in FTIR Platform

Hyphenated techniques are obtained when two different types of instruments are mated together. The purpose of hyphenated techniques is to allow multiple pieces of information to be obtained on the same sample by having two or more instruments working together. In GC-MS the gas chromatograph purifies the sample into its components and can quantify those components, and the MS identifies each component. This provides a powerful technique for purifying, identifying, and quantifying mixtures. Routinely available hyphenated instruments available in market are TG-IR, TGA-MS, TGA-GCMS, TGA-IR-GCMS. Wherein TGA instrument is usually hyphenated with IR, MS, GCMS or IR followed by GCMS. These studies allow for the ability of hyphenation of instruments from the same vendor enabling for time resolved experiments as the various events in the instruments triggered by relay box using the Spectrum™-TimeBase™ from PerkinElmer, which otherwise is limited when different instruments from different manufacturers are hooked up for combinatorial studies.

Latest innovation from PerkinElmer to effectively use the FTIR, new capability has been introduced called EGA 4000 which was also awarded the 2020 R&D World-100 award winner. As shown in Figure 4, it is the first device in the world to integrate in-sample-compartment thermogravimetric analysis with infrared spectroscopy. The Spectrum 10 software contains all the necessary controls for the EGA 4000, so the entire experiment can be carried out using a single software platform. The EGA 4000's ability to combine the two techniques of thermogravimetric analysis and infrared spectroscopy is an efficient means of identifying the components present in any sample. Unlike earlier Hyphenation instrument wherein TGA is coupled with FTIR. Here in EGA 4000, in-sample compartment TGA is integrated to achieve evolved gas analysis and similar to any other accessories like ATR, Gas Cell or transmission accessory can be replaced post the analysis. These give more flexibility to the FTIR instrument to study samples using ATR accessory followed by EGA to derive more in-depth information about the sample on the same platform.

Most analytical techniques used for paint analysis face several difficulties because of the complexity, the multitude of components, and the high viscosity of most paint formulations, which frequently restricts the technique to partial analysis, such as solvent analysis by GC or GC-MS. All components in a paint mixture can be examined using Fourier-transform infrared (FTIR) and an integrated sampling module for evolved gas analysis.

Here we have used EGA 4000 to analyze various paint formulations The experiments have shown that it is also feasible to estimate the relative amounts of the components, including solvent content and residual solids, based on the individual weight losses. The Spectrum 3's ability to switch between the ATR and the EGA 4000 provides the paint industry to study various formulations. Paints comprise several different ingredients, including pigments, fillers, binders, solvents, and additives, each of which has a specific purpose in the final product. Their formulation can incorporate a range of organic and inorganic compounds. Using EGA 4000 it is easy to distinguish between solvent and aqueous based paints using combination of thermal runs and comparing the evolved gases using inbuilt gas library and followed by FTIR-ATR measurement.

In summary pharmaceuticals, polymer industry followed by food continue to be the largest driver for the FTIR instrumentation markets. Vendors are optimistic that big-ticket purchasing will improve in the academic research market with enhanced focus on microplastics driven by FTIR microscopy. At the same time, their attention is turning to applied markets, such as environmental, petrochemicals and green hydrogen applications, which are gaining traction in India due to the country renewed focus on achieving an export-oriented economy. In all these markets FTIR forms a stable revenue base.

Reference

[1] *IBEF, Economic Survey 2022-2023.*

[2] *Strategic Directions International, Inc. Market Forecast (2021-2026).*

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CD Spectroscopy: An important Analytical Tool

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Circular Dichroism (CD) spectroscopy is a rapid and powerful analytical technique used for understanding the structural and conformational properties of biomolecules. Over the years, CD spectroscopy has widened its applications, not only as a tool for structural analysis but also as a valuable method in various scientific disciplines, including chemistry, biology, and pharmaceuticals. This article lights on the historical developments, current market trends, and future perspectives of CD spectroscopy.

Historical Development

Circular Dichroism spectroscopy had started taking shape long back in the 19th century. With the discovery of a phenomenon of rotating plane of polarised light by optically active crystals it was first come into picture. However, it was not until the 1950s and 1960s that the technique began to gain momentum in scientific research.

The key milestones in the historical development of CD spectroscopy include:

Discovery of Circular Dichroism

In 1811, a French scientist Dominique Arago also known as François Arago reported that light polarized by reflection could be split into two differently coloured beams by certain crystals.

Later in 1815, Jean-Baptiste Biot reported that rotation of plane of polarised light is not confined to crystals but can be observed in certain liquids and vapours, too. He was the one who concluded for the first time that rotation of plane of polarised light depends on the characteristic of individual molecule. He also used this finding in demonstration of chemical identity of sugars from sugar beets and sugar cane. Biot's work was taken forward by Louise Pasture who is credited for showing the power of optical rotation technique for future chemical research.

The term 'Circular polarization' was first introduced in 1922 in a memoire by Augustin Fresnel. He was the first to explain the conceptual difference between polarized and unpolarized light.

Further developments in the circular dichroism technique in 20th century was marked by the work of Aimé Cotton. In his work of studying optically active chiral compounds with polarised light, he discovered the large variation of optical rotation as a function of wavelength. The concept is now regarded as 'Cotton effect'. It was his time when the concept of 'Circular Dichroism' took a complete shape.

Hence, Jean-Baptiste Biot, Augustin Fresnel, and Aimé Cotton are

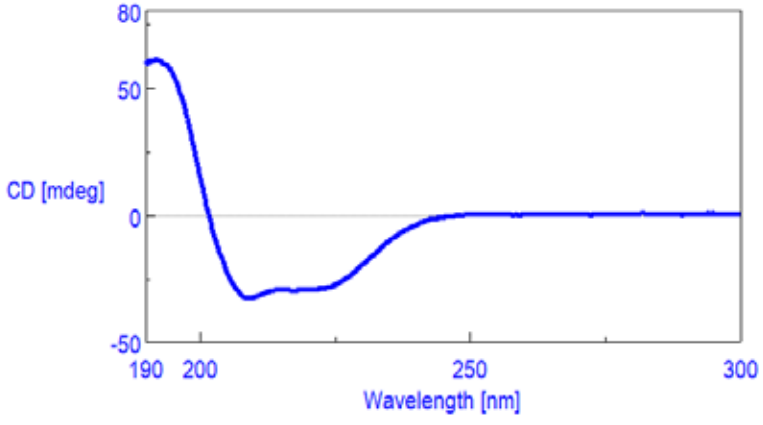

Figure 1: Representative CD Spectra of Alpha-Helix rich protein

together regarded as pioneer of circular dichroism.

Development of Instrumentation

It was the 1950s and 1960s that saw development of circular dichroism spectrometers.

Application in Structural Biology

In the 1970s, CD spectroscopy gained popularity in the field of structural biology, particularly for studying the secondary structures of proteins and nucleic acids.

The 1980s and 1990s witnessed significant developments in the quantitative analysis of CD data, enabling precise determination of protein and nucleic acid structures.

Till the dawn of biosimilars drug development, CD spectrometers were confined to fundamental research. But it did not stop the advancements in CD spectrometers. Developments such as vibrational circular dichroism (VCD) spectrometers or circularly polarised luminescence (CPL) spectrometers are the two prominent examples that have rising demands in biophysics or structural chemistry/ biology research.

Expansion into Pharmaceuticals and Biotechnology

CD spectroscopy found applications in the pharmaceutical and biotechnology industries in the late 20th century.

It became a vital tool for characterizing the secondary and tertiary structures of therapeutic proteins and nucleic acid-based drugs.

Current Market Trends

CD spectroscopy has established itself as a versatile technique, and its market has seen steady growth and diversification. Several key trends are shaping the current landscape of CD spectroscopy:

Instrumentation Advancements

Modern CD spectrometers are equipped with advanced technology, allowing for high-throughput data acquisition and increased sensitivity.

Automated sample handling and data analysis software have made CD spectroscopy more user-friendly and accessible.

Biopharmaceutical Applications

CD spectroscopy is extensively used in the biopharmaceutical industry for characterizing the conformation and stability of biotherapeutics, including monoclonal antibodies and vaccines.

It plays a crucial role in ensuring the quality and safety of biopharmaceutical products.

Structural Biology Insights

CD spectroscopy continues to be a valuable tool for studying the structural properties of proteins, nucleic acids, and other biomolecules.

It provides insights into protein folding, stability, and interactions, aiding in drug discovery and development.

Chiral Analysis

CD spectroscopy is essential in chiral analysis, allowing the differentiation of enantiomers in pharmaceuticals and agrochemicals.

Regulatory requirements for chiral purity in drug manufacturing have increased the demand for CD spectroscopy. For example, extension of CD spectroscopy in infrared region i.e. vibrational circular dichroism (VCD) has the applications in drug discovery. Its inclusion as a chiro-optical spectroscopy technique in US pharmacopoeia (Chapter 782) for assessment of absolute configuration of chiral drugs have guided pharmaceutical companies to opt for this technique.

Hrishikesh Joshi has about 12 years of experience in research and development. His area of expertise has been characterization of biotherapeutics particularly with spectroscopy techniques such as CD, fluorometry, FTIR, etc. In the past, he has been associated with some notable names in Indian biotech industry such as Lupin and Serum institute of India. Currently he works with Anatek Services Pvt. Ltd. as 'Application Manager' for its spectroscopy division.

Figure 2: Jasco CD Spectrometer (J-1500)

Academic and Research Applications

CD spectroscopy remains one of the widely used techniques in academic and research laboratories for a wide range of studies, from fundamental research to applied science.

It is used in the fields of chemistry, molecular biology, and materials science.

Global Market Expansion:

The market for CD spectrometers has expanded globally, with increased adoption in emerging markets in Asia, particularly in China and India.

Jasco Corporation is the world's leading manufacturer of CD spectrometers and they have developed a large research potential in the field of Biotechnology, Life science

and Biosimilars through constant innovation of application-oriented instrumentation and accessories.

Future Perspectives:

As we look ahead, the future of CD spectroscopy appears promising, with several emerging trends and developments expected to shape the field over the next five years:

High-Throughput and Automation

The demand for high-throughput screening in drug discovery and biopharmaceutical development will drive the development of CD spectrometers with enhanced automation, allowing for rapid data acquisition and analysis.

Innovations in Data Analysis

Advanced data analysis and machine learning algorithms will improve the interpretation of CD spectra, enabling researchers to extract more detailed structural information. For example, correlation of experimental VCD spectrum recorded by Jasco's Spectra Manager with theoretical VCD spectrum generated by software like Jaguar or Guassian can give useful insights in absolute configuration of chiral drugs.

Recently launched qHOS software from Jasco is one more such example that offers statistical similarity assessment of CD spectra. Particularly, qHOS enables scientists/ analysts to quantitatively assess not only CD spectroscopy data but also data from other spectroscopy techniques such as UV-Vis absorption spectroscopy, fluorescence spectroscopy, FTIR with globally accepted statistical methods.

Improvements in algorithms for secondary structure analysis of proteins will help researchers with deeper understanding. For example, much superior software like BeStSel offers more comprehensive secondary structure data as compared to some old software like CDNN or K2D2.

Regulatory Compliance

The importance of regulatory compliance in pharmaceuticals and biotechnology and its implementation by instrument manufacturers will drive the continued growth of CD spectroscopy in quality control and validation processes. Recently launch 21CFR compliant offline version of BeStSel software is an example of how regulatory requirements are driving development in CD spectroscopy.

Contract analytical laboratories

CD spectrometer despite the increasing utilization in fundamental and commercial research is a high capital investment instrument. It also requires skilled manpower. These challenges have opened the door for outsourcing business. Hence, 'Contract research and analysis laboratories' is one more rising sector for CD spectrometers.

Conclusion

Circular Dichroism (CD) spectroscopy has come a long way from its discovery in the 19th century to becoming an indispensable tool in various scientific disciplines, particularly in the biopharmaceutical industry and structural biology. The current market trends reflect its significance, with advanced instrumentation, biopharmaceutical applications, and chiral analysis driving its growth. Looking forward, the future of CD spectroscopy is bright. Continued advancements in instrumentation, development of data analysis tools, its applications in booming field of biotherapeutics and other emerging markets will propel the technique to new heights. As CD spectroscopy continues to evolve and adapt to the ever-changing landscape of science and technology, it remains an essential analytical tool for researchers, scientists, and professionals seeking to unlock the mysteries of molecular structure and function. Over the next five years and beyond, CD spectroscopy will undoubtedly play a pivotal role in shaping our understanding of the complex world of biomolecules and materials.

Trends in Life Science Instrumentation, Technology and Market Landscape in India

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Life Science Instrumentation covers various technology segments, making it the broadest category within the laboratory instrumentation field. This sector offers significant opportunities for ground-breaking advancements, exploration, and expansion while simultaneously serving diverse research markets. Nucleic acid-based methods, as well as protein and expression analysis, remain highly sought after for their ability to support cutting-edge research and specialized applications.

The life sciences industry in India is currently experiencing a significant transformation driven by rapid technological progress, changing market dynamics, and the convergence of pharmaceutical outsourcing and academic research. In this article, we embark on an in-depth exploration of the technological landscape, essential market trends, competitive dynamics, insights into applications, and the evolving technological framework that has fuelled the demand for life science instrumentation in India. We will closely examine crucial instruments such as microplate readers, cell counters, high content screening systems, small animal *in vivo* imaging devices, high throughput screening equipment and automation solutions.

Key Market Dynamics

Several dynamic factors fuel the life science instrumentation market in India:

Pharmaceutical Outsourcing: India's reputation as a global pharmaceutical hub has driven demand for advanced instrumentation. Pharmaceutical companies are increasingly outsourcing research, clinical trials, and drug development to Contract Research Organizations (CROs) that rely on state-of-the-art instruments[10].

Academic Research: Increased government funding for translational research, a growing emphasis on industry-academic partnerships within academic institutions and collaborations with international organizations have heightened the demand for state-of-the-art instrumentation[11].

Government Initiatives: Initiatives like 'Make in India' have stimulated domestic manufacturing of life science instruments, resulting in cost reduction, innovation stimulation and heightened competitiveness[4].

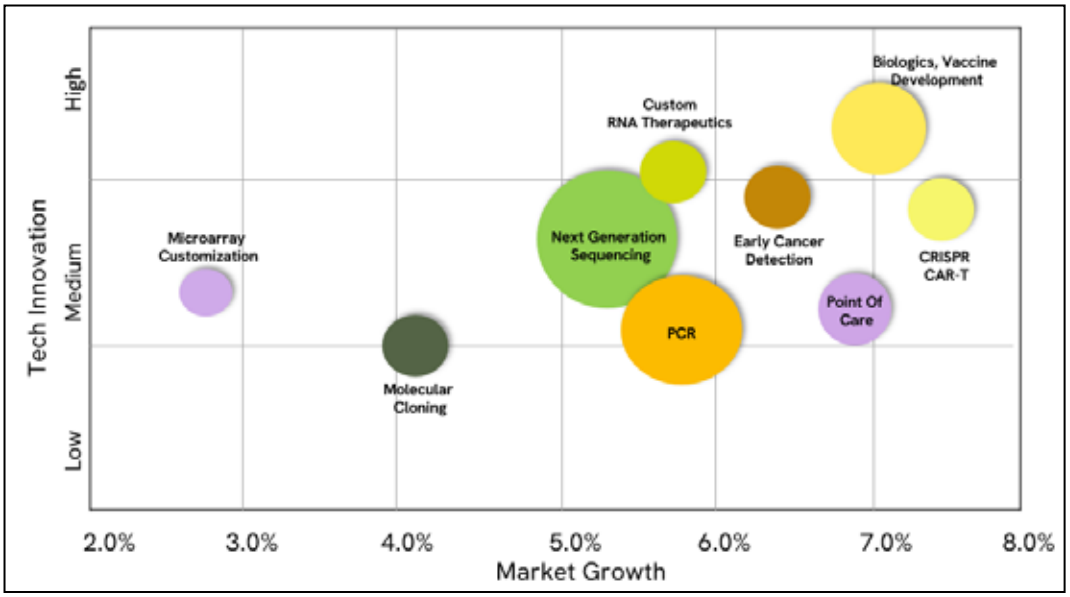
Healthcare Expansion: India's growing healthcare sector, propelled by rising healthcare spending and an increasing middle-class population necessitates advanced diagnostic and research tools, further amplifying instrument sales.

Technology, Application and Competitive Overview

India's life science instrumentation sector has embraced a wave of cutting-edge technologies, ushering in a new era of innovation across research, diagnostics, and drug development.

The bubble chart[5] illustrates the evolution of technological innovation and its corresponding market expansion. Notably, significant growth is evident in areas like Next-Generation Sequencing (NGS) and Polymerase Chain Reaction (PCR). Nevertheless, the most substantial advancements are observed in Point of Care technologies, cancer research and detection, biologics and cell and gene therapy. India stands out as a premier outsourcing partner, excelling in achieving drug research and innovation goals. Critical to attaining these objectives are the instrumental tools employed in the process.

Microplate Readers: These



instruments have witnessed a remarkable evolution, incorporating advanced detection technologies such as fluorescence, luminescence, and absorbance. Integration with automation systems and sophisticated data analytics tools have revolutionized throughput and data management, making them indispensable for drug discovery, molecular research and high-throughput screening.

- Monochromator-based microplate readers command a larger market share compared to their filter-based counterparts.
- The growth of pharmacology profiling within the domain of drug discovery applications is expected to play a significant role in propelling this expansion.
- Single detection technology based readers contributes highest in growth.
- Globally, Danaher currently maintains its position as the leading provider of microplate readers. Close contenders include Revvity, Tecan, Biotek, and Thermo[5].

Cell Counters: Modern cell counters offer precision, speed and user-friendly interfaces. The infusion of artificial intelligence (AI) algorithms has significantly improved cell identification and differentiation, benefiting both research and clinical applications.

- Demand for image-based cell counters drives growth of the market Globally.
- The pharma/bio sector will lead growth in the near term for cell counters, which are required for monitoring cell growth in both research and bioprocessing applications.
- Globally: Thermo and ChemoMetec share equal market share followed by Beckman Coulter, Nexcelom (Revvity) and Sigma-Millipore[5].

High Content Screening (HCS): HCS systems have undergone a transformative journey, enabling the simultaneous analysis of multiple cellular parameters. These systems now feature cutting-edge imaging techniques, automation, and machine learning algorithms, positioning them as crucial tools for cell-based assays, drug screening and disease modelling.

- *Total Pharma outsourcing growing annually at about 11% with a market potential of approximately US$ 54 billion[1]*
- *Total Outsourcing market size for CDMOs in India is ~2.4 BUS$ in 2021 and will become US$ 4B in 2025[2]*
- *India CRO Market Size Worth US$ 979.8 Million by 2030 at 7.50% CAGR[3]*
- *9 DBT-supported biotech parks and 60 BIRAC-supported bio-incubators[4].*
- *In the Union Budget 2023-24, the Department of Biotechnology (DBT) was allotted US$ 162.7 Million (Rs. 1,345 crore) to promote research and development.[4]*
- *Patient pool expected to increase over 20% in the next 10 years, mainly due to rise in population[4].*

- Demand for HCS drives majorly from CCD-based HCS, Confocal-based HCS and then Laser Scanning.

- In recent years, the market has been lifted by the utilization of pharmaceutical, biotechnology, and applied sciences, although the reduced demand for High Content Screening (HCS) due to the declining impact of COVID-19 has had a dampening effect. The near-term increase in demand is expected to be primarily fueled by applications in drug discovery.

- Globally: In the Confocal and Laser instrument market, Revvity, Danaher, and Thermo Fisher have a strong presence, whereas Sartorius, Cytiva dominates the market for CCD-based scanners[5].

Small Animal *In Vivo* Imaging: Innovations in this field have given birth to high-resolution imaging systems with multimodal capabilities and real-time monitoring capabilities, delivering unprecedented insights into disease progression, drug efficacy, and toxicological studies. Vital for preclinical studies, drug development, and cancer research.

- Optical imaging fuels growth in India, while globally, demand is evenly spread across MicroCT, PET, SPECT, MicroMRI, Optical and Ultrasound technologies.

- The pharmaceutical and biotech industry is the primary growth driver, with *in vivo* animal imaging often called pre-clinical imaging, crucial for drug testing before human trials.

- Globally: The leading vendors in the market are Revvity, Bruker, and FUJIFILM, VisualSonics[5].

Liquid Handling / Automation: Automation systems have streamlined laboratory workflows, reduced human error, and elevated efficiency across various life science applications, from sample preparation to data analysis. Streamline laboratory workflows across diverse applications.

- The pharmaceutical and biotech industry stands as the largest end market, propelled by the need for high-throughput capabilities in drug research.

- Revvity, Tecan, Hamilton, Beckman Coulter make up the top four leading vendors, collectively representing over half of the total vendor share[5].

Future Changes in Technology Trends

As technology continues to advance inexorably, several noteworthy trends are reshaping the life science instrumentation landscape in India.

Specialization: The specialization trend in the life science industry, with a focus on customization, service excellence, and technical support is particularly pronounced within the academia and research sector. Companies like Revvity *that* understand and cater to the specific needs of this sector are well-positioned to not only gain a competitive edge but also contribute significantly to the advancement of scientific knowledge and innovation through their collaborative efforts with researchers and institutions.

AI Integration: AI is becoming a pivotal component of instrumentation, enhancing data analysis, pattern recognition, and real-time decision-making, thereby augmenting research and diagnostics efficiency[7].

Miniaturization and Portability: The development of smaller, portable, energy saving, low waste producing instruments is gaining traction, enabling flexibility in research settings, point-of-care diagnostics and field studies[8].

Data Sharing and Collaboration:

Mayank Srivastava is a seasoned professional with over 20 years of experience in Sales, Marketing, and Product Management, having worked in leading organizations such as Advinus (now Adgyl), Thomson Reuters, PerkinElmer and Agilent in the Life Science, Food, Diagnostics and Pharma CROs and Consulting sectors. Currently, he serves as the Director of the Product and Application team at Revvity India. With his extensive industry background, Mayank has acquired a deep understanding of the unique dynamics and constantly evolving trends within these fields.

Market Estimation:

- *Multimode Reader: Global US$ 1B growth @ CAGR ~3.8%(5), India US$ ~25 M, growing 6% CAGR.(5,6)*
- *Cell Counters: Global US$ 275M, growing @ CAGR ~8%, India US$ ~11 M(5,6) growing 5% CAGR.*
- *High Content Screening (HCS): Global US$ 580M growing @CAGR ~8% , India US$ ~20M growing 6% CAGR(5,6). includes: CCD-based HCS, Confocal-based HCS, Laser Scanning.*
- *In-Vivo Imaging: Global US$ 650M growing @CAGR ~6%(5), India US$ ~15 M growing @CAGR 5%(5,6). includes MicroCT, PET, SPECT, Micro MRI, Optical, Ultrasound.*
- *Liquid Handling/ Automation: Global US$1.5B @5.3%, India US$15M growing @CAGR 6%, Includes Automated robotics, liquid handlers.*

Includes consumables, Service.

Cloud-based platforms are fostering data sharing and collaboration among researchers, enabling real-time analysis and global scientific cooperation[9].

Conclusion

TThe convergence of technology trends, market dynamics, pharmaceutical outsourcing and academic research is generating unprecedented demand for life science instrumentation in India. Instruments like microplate readers, cell counters, high content screening systems, small animal *in vivo* imaging devices, high throughput screening equipment, Radiolabel Techniques, automation solutions, and those associated with cell and gene therapy have become the foundation of scientific research, diagnostics, and drug development.

To thrive in this dynamic landscape, manufacturers and service providers must remain agile, adapt to shifting research priorities, evolving regulatory landscapes, and the diverse needs of academia, pharmaceutical firms, biotech startups, and healthcare institutions. Meeting these demands is imperative for companies looking to establish a dominant presence in India's thriving life science instrumentation market, where innovation continues to drive the life sciences industry into an exciting future.

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Next Generation Sequencing - Market Forecast and Opportunities

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Since the DNA was discovered, recognition of the genome structure and function has enormously increased. This ever-increasing knowledge and its applications in molecular cloning, breeding, evolution studies and finding morbific genes would not exist without sequencing technologies. The first sequencing technique was developed by Frederic Sanger in 1977, which became the pioneer in 'First generation' commercial sequencing applications. In 1987, Applied Biosystems (AB) introduced first automatic sequencing machine (AB370), which made the sequencing process faster and accurate. When the Human Genome Project was officially completed in 2003, Sanger sequencing was the main tool used.

Next came the second-generation sequencing technique (or next-gen sequencing or NGS as it is popularly known) that showcases massively parallel analysis, high throughput and reduced cost. Technology advancement in NGS paved the way for a series of NGS high-throughput instrument launches from 2005 onwards - 454 Lifesciences (now Roche), SOLiD (ABI now Life Technologies), Solexa (Illumina) and in 2010 Ion Torrent (now Thermo). These remarkable systems demonstrate their own advantages like read length, accuracy and cost. These second-generation techniques and instruments were widely employed in basic research.

Further developments in sequencing methods opened the stage for the third-generation sequencers, which shortens the DNA preparation time to few hours and allows for longer DNA read lengths than NGS. Enter PacBio (the signal, the fluorescence) and Nanopore (the electric current), where signal is captured in real time and monitored during the enzymatic reaction.

NGS Market Scenario

The global sequencing market is expected to be worth of US$37.99 billion by 2032 from US$ 9.69 in 2022 with a annual growth rate (CAGR) of 14.7% during the period 2022-2032.

Asia Pacific NGS market size is valued at USD 570 million in 2022 and is poised to grow at a CAGR of 24% from 2023-2029. It is considered to be the fastest growing marketing in NGS. Typically, the Indian market is about 7-10% of Asia Pacific market.

Key players in this space are Illumina, Thermo Scientific, PacBio and Oxford Nanopore, MGI etc. Majority market share is taken by Illumina with its proven short read technology. MGI, Thermo are short read players who enjoy about 8-10% of market. Long read players are relatively new entrants in this market and this space is occupied by ONT and PacBio.

With the introduction of PacBio's new launches end of 2022, the market scenario is certain to change. PacBio's proprietary launches of HiFi and SBB (sequencing by binding) (*www.pacbio.com*) are showing high double-digit growth in the last year (*www.seekingalpha.com*). In addition, several new entrants like Element Biosciences, Ultima genomics and Singular Genomics are bringing about changes and competition to the NGS industry with new technology and low run costs. The market share is expected to be altered considerably due to these new entrants and products.

Key players and their technology

Significant players in the ultra-competitive sequencing market include companies like Agilent Technologies Inc., Bio-Rad Laboratories Inc., Danaher Corporation, Roche, Illumina Inc., Thermo Scientific, MGI Tech, Merck KGaA, Revvity (previously Perkin Elmer Inc.,) etc. While most of these players are solely involved in the sequencing consumables market, the following are the major players

in the instrumentation market.

Illumina

Illumina NGS instruments is the world leader in sequencing solutions and they have been adopted by leading institutions and clinicians around the globe. They have been the production platforms for many genome centres. Illumina sequencing technology leverages sequencing by synthesis (SBS) technology – tracking the addition of labeled nucleotides as the DNA chain is copied – in a massively parallel fashion. Illumina sequencing systems can deliver data output ranging from 300 kilobases up to multiple terabases in a single run, depending on instrument type and configuration. Each sequencing run delivers good data quality and performance, with flexible throughput and simple, streamlined workflows for every kind of researcher, for every scale of study. (Source: www.illumina.com).

PacBio

Advanced scientific discoveries require sequencing data that is both accurate and complete. PacBio sequencing technology leads to a different type of long reads, known as highly accurate long reads, or HiFi reads.

HiFi reads offer long-read sequencing of up to 25,000 bp in a single run with the added accuracy of 99.9%, on par with short reads and Sanger sequencing. HiFi reads are produced using circular consensus sequencing (CCS) mode on PacBio long-read systems. HiFi reads are effective across a wide range of application, from whole genome sequencing for *de-novo* assembly, comprehensive variant detection, epigenetic characterization, RNA sequencing, metagenomics and more.

PacBio's newly launched long-read system 'Revio' adds affordability, high throughput, and ease-of-use laid on a strong foundation of long reads, exceptional accuracy and direct methylation detection. Revio brings cost economy and is well-fitted for the growing diagnostics industry. India's first installation happens to be in the research field of clinical oncology. One more new launch is an innovative bench top short-read DNA sequencing platform 'Onso' with an extraordinary accuracy using sequencing by binding (SBB) technology with the ultra-high Q40+ data quality.

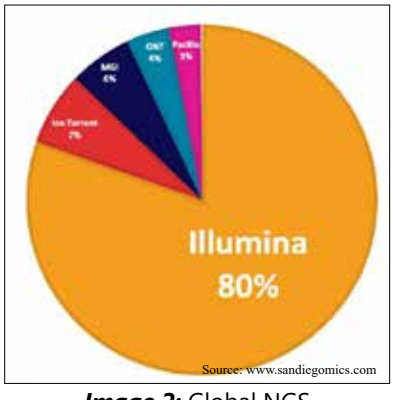

Image 2: Global NGS Market share 2022

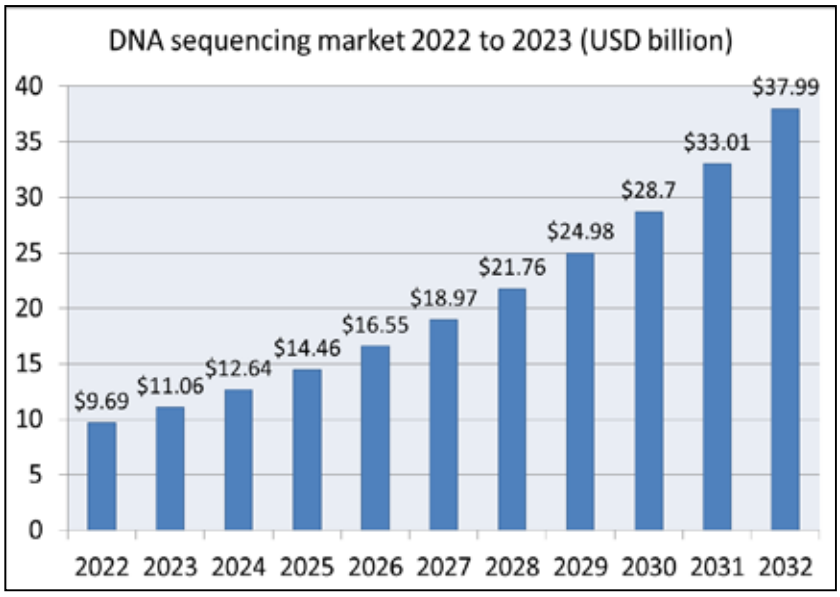

Image 1: *DNA sequencing market size, 2022 to 2032 (USD billion)*

Oxford Nanopore

Nanopore sequencing is a scalable technology that enables direct, real-time analysis of long DNA or RNA fragments. It works by monitoring changes to an electrical current as nucleic acids are passed through a protein nanopore. The resulting signal is decoded to provide the specific DNA or RNA sequence. Advantages of real-time data streaming include rapid access to time critical information (e.g. pathogen identification), the generation of early sample insights, and the facility to stop sequencing once a result has been achieved enabling washing and reuse of the flow cell.

Thermo Fisher Scientific

Ion Torrent's Integrated Sequencer automates next-generation sequencing (NGS) library preparation, sequencing, and analysis. Ion Torrent exploits the fact that addition of a dNTP to a DNA polymer releases a hydrogen ion. We measure the pH change resulting from those hydrogen ions using semiconductors,

simultaneously measuring millions of such changes to determine the sequence of each fragment. The semiconductor approach unlike optics or modified nucleotides used in other NGS technologies helps you implement a fast and simple workflow that scales to your research needs across multiple applications.

Element Biosciences

The scientific founders have applied their expertise in reagent design to ensure their machines can produce higher quality data at a lower price than Illumina. A reagent containing multivalent avidite substrates and an engineered polymerase are combined with DNA polonies inside a flow-cell. The engineered polymerase binds to the free 3′ ends of the primer-template of a polony and selects the correct cognate avidite *via* base-pairing discrimination. The multivalent avidite interacts with multiple polymerase on one polony to create avidity binding that reduces the effective Kd of the avidite substrates 100-fold compared with a monovalent dye-labeled nucleotide, allowing productive binding of nanomolar concentrations. Imaging of fluorescent, bound avidites enables base classification.

MGI

MGI's DNA sequencing technology utilizes the state-of-art core technology called DNBSEQ. DNA nano balls (DNBs) are pumped with by the fluidics system and loaded onto a patterned array chip. The sequencing reaction starts by pumping sequencing reagents containing fluorescently-labelled dNTP probes and DNA polymerase. Images are taken after the fluorescently-labelled probes on the DNB are existed with lasers. The images are then converted into a digital signal using MGI's propriety software. This information is then used to determine the DNA sequence of the sample.

> ***DNA sequencing methodologies have application in the fields of biotech, forensic biology, medical diagnosis, biological systematics, and virology. NGS allows a full genome of any organisms to be sequenced in a less time. Using NGS in clinical diagnostics expedite the exciting possibilities.***

Application Areas and Market Opportunities

DNA sequencing methodologies has application in the fields of biotech, forensic biology, medical diagnosis, biological systematics, and virology. NGS allows a full genome of any organisms to be sequenced in a less time. Using NGS in clinical diagnostics expedites the exciting possibilities. Each of the above mentioned areas has a decisive influence on market expansion.

R&D: In the public sector, NGS is being used in whole genome sequencing of plant, animal, insect or microbial genomes of indigenous organisms, to create national databases and also public health surveillance. Utilizing in human genomics involve study and detection of rare diseases, oncology, neuro-degenerative diseases and infectious diseases using structural variant detection. Gut microbiome projects, population genetics, rare disease study etc. are some projects being initiated by the Govt of India. According to the Indian Council of Medical Research (ICMR) (March, 2022), India has 84 available NGS facilities across the country.

Diagnostics: The global clinical

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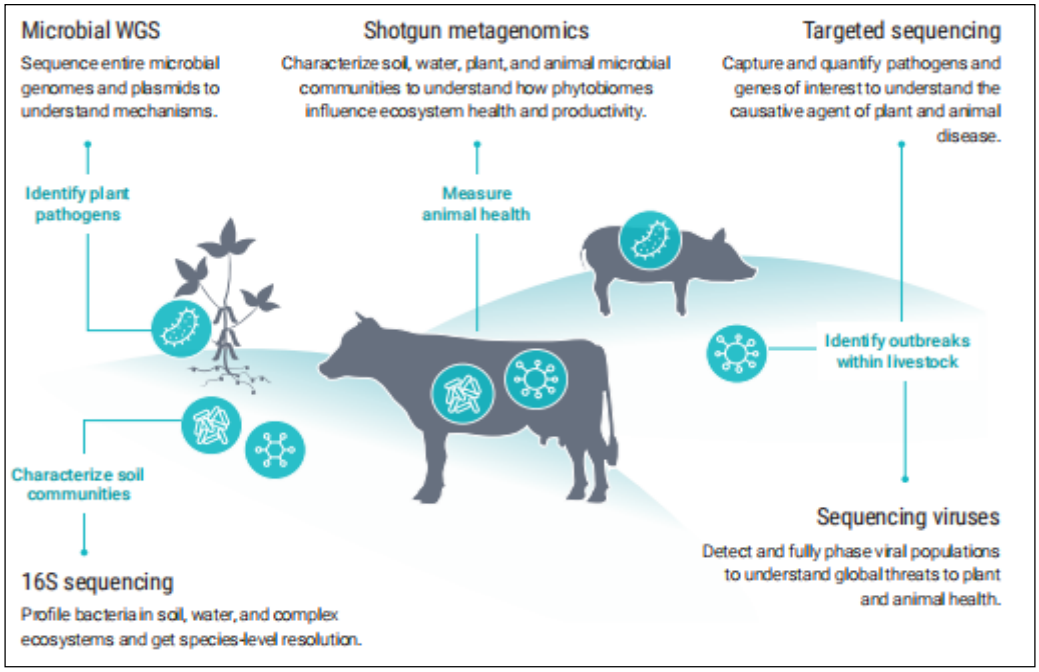

Image 3: *Applications of PacBio long read sequencing*

oncology NGS market is estimated to be around US$ 449.4 million in 2022 and this is expected to be CAGR 16.3% for the period 2022-2029. Consequently, the market of clinical oncology NGS and its developments is expected to have a positive growth in the near future. Several studies have shown the utility of NGS in identifying the clinically actionable mutations in cancer patients. The Genomics Evidence Neoplasia Information Exchange (GENIE) an international data sharing consortium sequenced 30% tumour across several cancers could be targeted by an existing targeted therapy (AACR project, 2017). While at present, many cancer patients are unable to access care options due to the high cost of NGS and NGS-matched therapy, cost per test (CPT) are reducing everyday with evolution of new technology and increase in competitive players in the market. Genetic testing for ancestry and health predisposition are on the rise and personalised genomics is designed to help people understand their risk for developing inheritable health conditions.

COVID-19: The COVID -19 pandemic dramatically increased the demand for DNA sequencing to develop therapeutics and diagnostics. In November 2021, the Union Minister of State for Science and Technology, India announced that Department of Biotechnology (DBT) had completed the genome sequencing for COVID-19, which was further made available to academia and industry R&D for product development. The sequencing of different variants of COVID-19 was done by National Institute of Virology (NIV, Pune) and published. Sequencing the virus helped monitor the variant changes and to understand the genetic epidemiology and recent times. Genetic sequencing is now continued in public surveillance projects to keep a watch on how the virus spreads and evolves.

Population Genetics - Human population genomics focuses on the entire human genome and the genome-wide association effects to identify genetic variations, the ancestry background, demographics and microevolution in populations. NGS applications make this possible to compare genomes in greater quantities and capture the diversity and variations of adaptations to a specific environment. By analysing the roles of evolutionary processes such as mutation, genetic drift and natural selection in shaping up the individual loci and across the genome populations, NGS is a powerful tool to map populations.

NGS-AI is cutting edge area, most active in genomics and bioinformatics. One of the main challenges in NGS is data analysis, due to large amount of data generation by each sequencing run. By using AI platforms, sequencing data analysis can be done by developing innovative algorithms without the need for subject matter experts. AI allows us to investigate the orthogonal data sets, enabling description of any given biological sample in an as-yet unprecedented

detail, from the genome structure to the expression and regulation of genes.

Challenges

Major challenges in the NGS market are affordability and skill. Earlier the high costs of NGS sequencing consumables or services made it a low priority in diagnostics tests and in academic markets. The trend is changing as reagent costs are dropping and becoming more affordable, even for long-read platform. National guidelines on the use of clinical genomics in India to improve patient care is much needed. Availability of skilled resources, especially for big data and bioinformatics is a key challenge. Integration of computational technologies like Bioinformatics, Artificial Intelligence (AI), Machine Learning (ML) and biological sciences is need of the hour.

Summary

- The global sequencing market is anticipated to reach US$37.99 billion in value by by 2032, up from US$9.69 billion in 2022, with a compounded annual growth rate (CAGR) of 14.7% from 2023 to 2032.
- The Asia Pacific region is expected to expand at the fastest CAGR of 17.3% during 2023-2030, due to the increasing adoption of NGS in diagnostics. Over the projected period, more applications of DNA sequencing are anticipated, which would increase the utilization of consumables.
- Advancements in technology are creating an entry of new innovative instruments and reagents in the market and are crucial in bringing down the price of genome sequencing and making it accessible to a larger scientific and clinical community.
- Application of sequencing methods is expanding in every field from academic research to diagnostics and clinical healthcare, vaccine industry and even food industries where gut microbiome data becomes essential information.
- Government's recognition and emergence of various projects will further help this growing market to develop and reach the needy patient population.

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The New Dimension of Confocal Imaging: TauSense

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STELLARIS the new Redefined Confocal Platform

In modern biological research, necessity for imaging is increasing very rapidly, as everyone started to accept that 'seeing is believing'. The rapid advancement of biological research necessarily demands to observe the small sub-cellular/ molecular objects which are much smaller than the traditional resolution limit of conventional light microscope. To address that, microscopy techniques, especially confocal microscopy has become the leading technical platform to enhance the imaging limits to satisfy modern scientists' overall needs. That's why in recent years, development of confocal microscopy has undergone revolutions to match the demands of present-day and future research.

With the STELLARIS confocal platform, Leica has re-imagined confocal microscopy to get more closer to the truth. This confocal platform has provided the opportunity to measure the functional information buried in any biological sample on the fly just with a single click of a button. This new approach not only enables to extract functional information from biological samples, but also enables staining free imaging and can track physiological changes in live samples.

The Beauty of Fluorescence Life-Time and TauSense

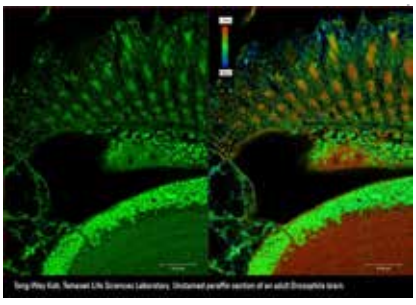
FLIM or Fluorescence-lifetime imaging microscopy is an imaging technique, built majorly on confocal microscopy platform based on the differences in the exponential decay rate of the photon emission from any fluorophore. The advantage of FLIM is that the photon emission rate or the lifetime of any fluorophore is inherent property of that particular dye and doesn't depend on any of the instrument parameters like objective magnification, laser power or detector sensitivity, which normally play big roles in case of intensity based conventional confocal measurements.

Fluorescence lifetime of any dye in fact changes depending on the fluorophore's microenvironment such as pH, metabolic or redox conditions or ion concentration, and this potential information was always there in the samples to be utilized. Leica has developed a unique set of tools to explore this potential to understand the function of molecules within the cellular environment and get an additional dimension of information, with just a click of a button, that can give

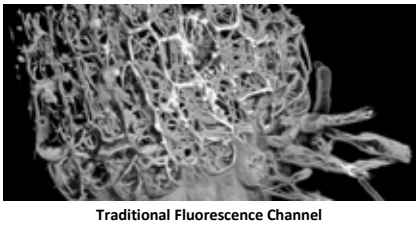
immense value the modern day and future biological research. The new fluorescence intensity independent measurement tool is called **TauSense** and consists of four different imaging modalities: **TauContrast, TauGating, TauSeparation and TauInteraction**.

TauSense

This set of tools, TauSense, provides the potential to extract a new dimension of information, which are usually hidden fluorescence lifetime-based information of any fluorophore, from every sample and increase the scientific impact of any research using fluorescence lifetime-based information to explore the function of molecules in their cellular context. Through this one can gain immediate access to functional information of samples including cell signaling, metabolic status, pH and ion concentration.



Unstained section of adult Drosophila brain: Normal fluorescence Channel in the left and TauSense channel in the right



Traditional Fluorescence Channel

The four modalities of TauSense are: **TauContrast, TauGating, TauSeparation and TauInteraction**.

TauContrast provides immediate access to functional information such as metabolic status, pH and ion concentration by identifying these changes.

TauGating helps you to maximize detection efficiency by removing unwanted signals while preserving the desired fluorescence.

TauSeparation can differentiate species based on their fluorescence lifetime, so dyes with similar or overlapping spectra can be distinguish separately.

TauInteraction provides most accurate and reliable way of measuring molecular interactions i.e. fluorescence lifetime based FRET.

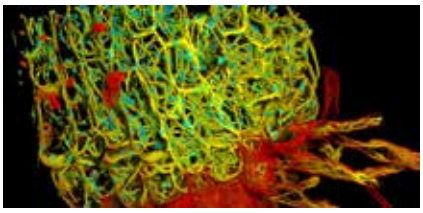
TauContrast

TauContrast provides immediate access to functional information such as metabolic status, pH and ion concentration by identifying these changes.

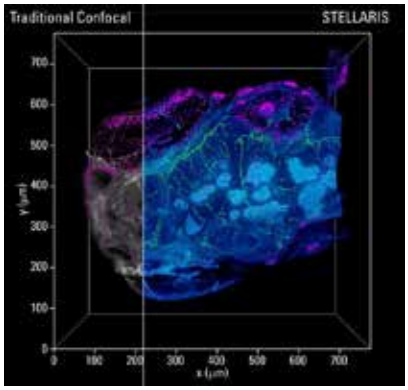
TauContrast generates images from the average photon arrival time in each pixel and the number of photon counts (fluorescence intensity). Different average photon arrival times produce contrast in the image based on the effect of their microenvironments (e.g. high calcium vs. low calcium conditions).

TauContrast is based on the following working principle:

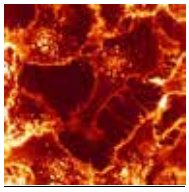
Instant lifetime-based information, with one click Simultaneous with



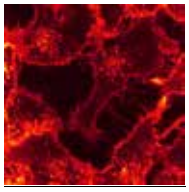
TauSense



TauContrast Image



Traditional Confocal Detection



TauGating: Remove unwanted signal

intensity detection Pixel by pixel readout of the mean photon arrival time

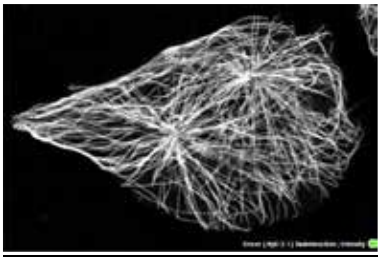
TauGating

TauGating helps to maximize detection efficiency by removing unwanted fluorescence while preserving the desired signal.

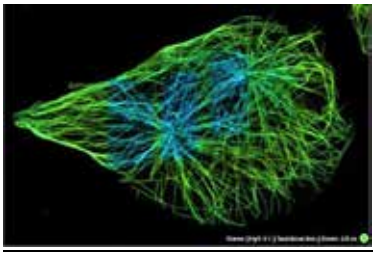
While imaging any sample one may come across fluorescence contributions such as intrinsic fluorescence, pigments, or reflections, which may overlap

Dr Manoj Manna is heading the product and application team of LSR division at Leica Microsystems. He takes care of technical discussions, presentations, product demonstrations and user trainings of confocal, super resolution, FLIM and high-end imaging systems. He was previously associated with DSS Imagetech Pvt Ltd., and holds a Ph.D in Biophysics from National University of Singapore & M.Sc in Physical Chemistry.

- *High-end microscopy, namely Confocal microscopy, Super-Resolution microscopy, and Fluorescence life-time based imaging techniques are majorly used in the field of Biotechnology, Molecular Biology, Developmental Biology, Spatial Biology, Nanotechnology, Biochemistry, Biophysics, Chemistry, Bio-Medical research including cancer biology, Stem Cell research and similar fields.*
- *Market for these kind of instruments in India was mainly concentrated in Government Academic institutions and Government Research institutions until last decade. Recently Private Academic institutes and Private Research centres are also showing interest to buy these high-end imaging systems.*
- *As a result, high-end microscopy market in India is growing considerably and new manufacturers across the globe have started focusing in Indian market. At present the confocal and confocal platform based high-end microscopy market is about $6.5 to 7 Million per year.*



Traditional Intensity Image



TauInteraction Image

with the desired fluorescence signal, making the images more difficult to interpret or even unusable. Elimination of unwanted fluorescence contributions is possible with TauGating, which helps to maximize detection efficiency by removing unwanted fluorescence while preserving the desired signal.

TauGating identifies the different photon arrival times from the fluorescent signals, so you can eliminate those that come from unspecific signal (time-window) contributions.

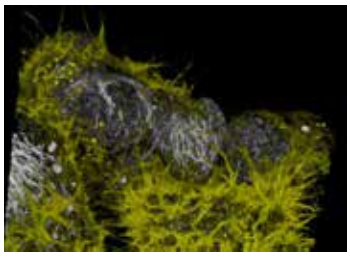
TauSeparation

TauSeparation can differentiate species based on their fluorescence lifetime, so dyes with similar or overlapping spectra, or dyes from inherent autofluorescence of the sample can be distinguished separately. Also, if any single dye exhibits different lifetimes in different physiological conditions, e.g., lysosomal marker in early endosome, in late endosome and in lysosome, can easily be separated efficiently using TauSeparation.

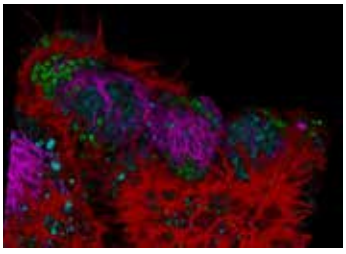
There are two features in TauSeparation:

TauScan: Display a diagram of lifetime components, identified by a gate-based multi-component fit.

TauSeparation: Separation of components based on lifetime into different channels, on the fly.



Traditional Intensity Image
4 dyes in Two spectral range



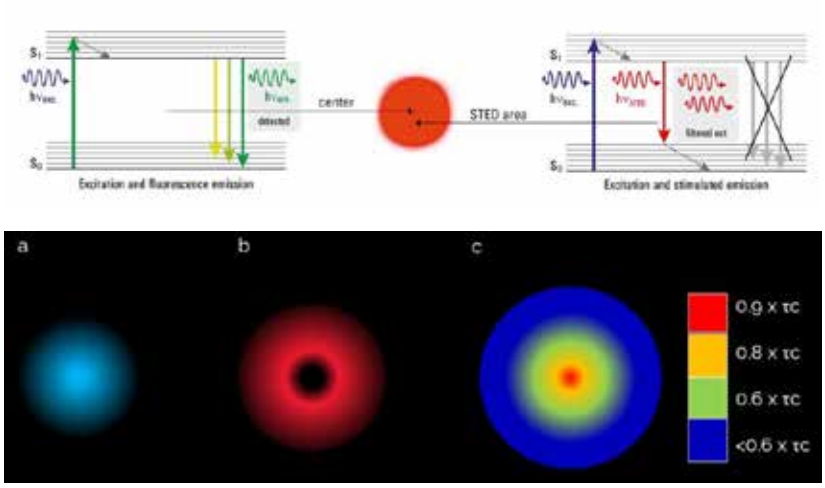
TauSeparation Image
4dyes, 4 distinct colours

TauInteraction:

Broadly speaking, there are at least three types of molecular interactions: nucleic acid-protein, protein-protein, and small molecules-protein. The tool of choice to experimentally confirm these interactions between two molecules is through Förster Resonant Energy Transfer or FRET. Among different FRET techniques, FLIM-FRET remains the gold standard approach because in this method the FRET readout depends only on the donor fluorescence lifetime changes, thus avoids most of the assumptions needed for intensity-based methods.

Here the experimentally measured lifetime of the donor dye in the absense of the acceptor i.e., without interaction with acceptor, and lifetime of the donor dye in the presence of the acceptor i.e., while interacting with acceptor are normally compared to get the extent of interaction. With **TauInteraction**, it's now just a matter of one click to measure that molecular interaction.

Donor only sample will be necessary as a reference for calculating the TauInteraction image.



Schematic of Gaussian excitation and STED profile, the fluorescence lifetime is shorter where the depletion is stronger

TauSTED: Life-Time Improving RESOLUTION

Fluorescence lifetime provides a new perspective for super-resolution STED nanoscopy. With the unique TauSTED functionality from Leica, the scientific research will benefit from super-resolution STED offering excellent performance with a much lower light dose and getting rid of undesired background signal.

TauSTED combines the optical signals from STED and the photophysical information from the fluorescence lifetime at unprecedented speeds. This new approach uses phasor analysis in a novel way. TauSTED enables an increased STED resolution down to **~30 nm** and elimination of uncorrelated background noise, even at low excitation and STED powers, enabling long time-lapse live-cell nanoscopy.

Access to the fluorescence lifetime-based information allows to increase image quality (signal-to-noise), eliminate photons from the background using physical principles, and push the resolution beyond the limits of intensity-based STED, no matter which excitation and STED line (592, 660, 775) is used.

TauSTED: Gentle super-resolution for extended live-cell imaging

The lower excitation and STED light dose translate into protection for the specimen. This capability empowers longer time-lapse experiments, i.e., more frames, or larger volume imaging without sacrificing spatial resolution.

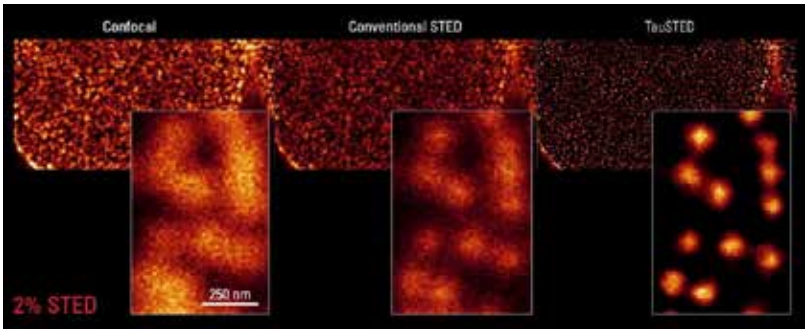
The most suitable STED fluorophores are those that emit in the far-red range, but these dyes, if used together, show a strong spectral overlap and cannot be combined in conventional STED with intensity-based only readout.

With TauSTED, it is possible to take advantage of the usage of these most suitable STED fluorophores, and perform multi-colour STED with lifetime-based species separation still delivering the highest resolution of about ~30 nm.

From live cell to big-tissue imaging, from super-sensitivity to super-resolution imaging, life-time based imaging approach by **TauSense** is made to generate cutting-edge and most reliable data from every sample to bring any research result most close to the **TRUTH**.

Market segment and Growth

The major technique described here, **TauSense**, is based on **Fluorescence-lifetime imaging microscopy** and was mainly being used by physicists and some bio-physicists. This is a technique which has not been used by biologists much due to it's complex instrumentation in the past. Leica has made the experimental usage extremely user friendly and simplified interpretation of the data to make it more popular in the field of biology as well. Globally it have become quite popular since its launch in 2020, hope it will soon see rapid growth in Indian market as well.



Innovation in the Lab - Solutions for Accuracy & Compliance

Pravin Jain,
Head of Lab Division,
Mettler-Toledo India Pvt Ltd.,
Mumbai

METTLER TOLEDO's precision instruments are the foundation of accuracy, speed and quality for research and quality control labs all over the world. Our comprehensive product range provides you with flexibility and precision in every application. See the product range overview below and discover all the ways we can help you deliver timely, reliable analytical results.

Peak Performance, Effortless Compliance with XPR Analytical Balances

There can be no compromise when you need accurate results. Thanks to smart quality assurance features, XPR analytical balances deliver valid results first time, every time. Seamlessly integrating into your existing information system, XPR analytical balances support the highest requirements for security, efficiency, and compliance.

With a range of intelligent quality assurance functions, you can depend on XPR to deliver right-first-time results. The patented StaticDetect™ technology, used in combination with the optional ionizing module, offers a complete electrostatic detection and elimination system to ensure accurate weighing results and highest process security. Optional modules and accessories make it easy to customize your XPR analytical balance to perfectly fit your process needs and improve comfort of everyday weighing. Even in highly regulated environments, XPR balances integrate seamlessly into your processes.

The weighing principle of METTLER TOLEDO analytical balances is based on electromagnetic force compensation. The weighing cell inside the balance housing creates a counteracting electromagnetic force to the object that has been placed on the weighing pan. The analytical balance interprets the magnitude of this compensating electromagnetic force as the weight of the object. The result is displayed on the balance terminal in the appropriate unit (grams, milligrams, micrograms, etc.).

Pravin Jain has more than 23 years of experience in various industries like Pharmaceuticals, Life Sciences, Bio-pharmaceuticals, Analytical Chemistry, etc. He is a Graduate in Chemistry with Post Graduate in Marketing Management. He has been working with Mettler-Toledo for past 11 years and currently heading the Laboratory Division. In addition to it he also heads the Global Key Account Management in India.

The weighing pan of an analytical laboratory balance (0.1 mg readability or smaller) is placed inside a draft shield, which protects the sample and container from external environmental influences like air drafts, improving general weighing performance. This is particularly important in analytical weighing when the accuracy of results is of utmost importance.

Analytical balances are used for simple weighing applications, as well as for standard and sample preparation, formulation, density measurement, filter weighing, etc.

Eliminate Static

StaticDetect measures the weighing error due to electrostatic charging and provides a warning if tolerances are exceeded. In combination with the optional ionizer, you have a unique solution that guarantees static-free weighing.

Right-First-Time Results

The integrated StatusLight™, LevelControl and GWP Approved work actively together to ensure all the relevant conditions for correct weighing are satisfied, giving you the reassurance that your results are valid.

Easy Automation Upgrade

Optional modules make it easy for you to quickly upgrade your balance to provide automated powder and / or liquid dosing. Automated dosing enables you to achieve a level of accuracy that is impossible to match in a manual process.

Effortless Data Integrity

Connect all your Excellence laboratory instruments to LabX™ software for full support with regulatory compliance. LabX™ helps you meet FDA ALCOA+ requirements for data integrity.

Advantages of METTLER TOLEDO's Analytical Balances

1) Automated Weighing – With optional powder & liquid dispensing modules, XPR analytical balances are easily upgraded to prepare samples and solutions in a fully automatic process.

2) Easy Cleaning – Cleaning your analytical balance is quick & easy, thanks to clever design features, such as fast release draft shields & hanging weighing pans.

3) Easy Documentation – Simplify results handling & documentation with our EasyDirect Balance data management software for Advanced & Standard level analytical balances.

- ***Indian weighing market is ~USD 23M in which the high end market is ~ 30%***
- ***Key trends include Automation, Digitalization, Regulatory Compliance, Safety, and Sustainability, to name a few***
- ***Cloud-based software demand in high-end equipment is gaining momentum***
- ***Expansion in sectors like Biopharma, CRO/CDMO, and Testing Labs are creating new opportunities for technology upgradation, and some key investments to watch are in segments like Battery and Semiconductors.***
- ***Latest Revisions in Global pharmacopeia highlights the significance of Balance calibration and adherence to Good Weighing Practices(GWP)***
- ***India is also very recently recognized as a OIML certifying country for measuring and precision instruments which will boost domestic exports***
- ***Major global players are Mettler Toledo, Sartorius, Shimadzu, and Ohaus***

Efficiency is increasingly important as labs are obliged to generate results quickly, compliantly, and cost-effectively, often with limited resources. Improvements to Lean operations in modern analytical labs can include device standardization, modularity, streamlining of workflows, optimization of workplaces, compatible software / networks, and competent services etc.,

4) Comprehensive Data Management – For our Excellence level analytical balances, LabX™ laboratory software takes care of all data automati*cally,* provides centralized control, and assists in compliance with 21 CFR part 11.

5) High - Performance Weighing Cells – METTLER TOLEDO weighing cells are expertly designed & precisely engineered to deliver accurate & reliable results.

6) Robustly Built for Longevity – Metal casings, overload protection, and high-quality materials ensure your analytical balance will perform reliably for many years to come.

7) Avoid the Hidden Errors Caused by Static – Our antistatic solutions help to eliminate electrostatic charges and thus prevent one of the major hidden sources of weighing errors. XPR analytical balances also have static detection technology.

Optimizing Workplaces and Workflows

Efficiency is increasingly important in the laboratory, as labs are obliged to generate results quickly, compliantly, and cost-effectively, often with limited resources.

Lean Management and Lean Lab imply optimized efficiency, concomitant with the minimization of any activities that do not add value: namely, of the 8 different types of waste that result in unplanned laboratory 'DOWNTIME': Defects, Overproduction, Waiting time, Non-engagement of all employees, Transportation, Inventory, Motion/distances, Extra processing.

TOC Analysers - Market Trends

Ch.Vijay Kumar
Managing Director,
Swan Environmental Private Limited
Hyderabad

Analysis of water before use is customary since the industrial revolution. These methods have evolved over time. Currently TOC analysis is used in wide applications such as regulatory compliance requirement in pharmaceutical and in environmental analysis where it is the best option over BOD and COD.

TOC analysis is an indispensable tool offering deep insights about quality of Source water, Drinking water, Pure water, Industrial Process water and Waste water. Global Adaptation and Regulatory Policies will project a good market for TOC analysers.

Organic Pollution of Water

Organics are ubiquitous to all waters and provide nutrition to aquatic living organisms. Excess organics viz., proteins, carbohydrates, fats and nucleic acids degrade the quality of water. A variety of Emerging Organic Contaminants (EOCs) were discovered in water sources in the past few decades due to Industrial discharges, hazardous waste dumps, domestic sewage, agriculture activities etc.

The organic pollution in water can be measured using Sum Parameters like BOD, COD, TOC. TOC analysis of water is easy as it is highly accurate; the analysis doesn't involve hazardous chemicals and gives results in minutes. Therefore, there is a global tendency to replace COD/BOD measurements with TOC measurement.

> ***Shimadzu is a global leader in TOC analysers and Shimadzu in the year 1984 invented the 680°C catalytic combustion method to take care of the salt fusion issues commonly faced in high temperature catalytic combustion methods and today it is the world standard over years for TOC measurements.***

TOC Analysis of Water

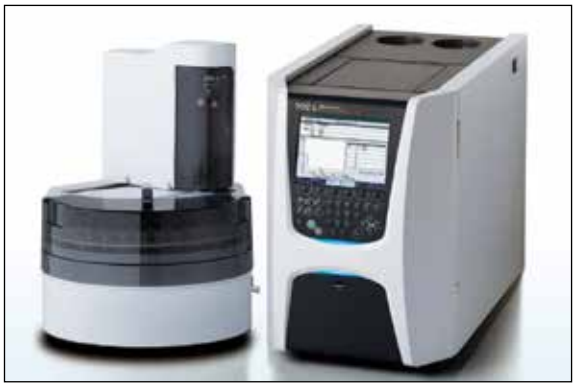
TOC is 'Measure of amount of Total Organic Carbon present in different matrix'. Lower the TOC, better the quality of water and vice versa. TOC has been widely recognized as an index of water quality, in terms of total index of organic substance in water.

Two methods are available for measuring TOC. One analysis technique involves measuring Total Carbon (TC) and Inorganic Carbon (IC), then TOC is calculated by subtraction of the IC value from the TC of the sample. Another method which is more common, directly measures TOC in the sample by removing IC and measurement of the balance as TOC.

TOC Analyzer Market in India – Past Scenario

The TOC analyzer market grew by CAGR : 7.96% in terms of volume (units) during FY2017-2022, from 661 units in FY2017 to 969 units in FY2022. In terms of value (INR) the market grew by CAGR: 7.63% during FY2017-2022, from 117.86 Cr in FY2017 to 170.15 Cr in FY2022.

There is no strong domestic manufacturing base in India for TOC analyzers. Most of the analysers are imported. The initial COVID-19 outbreak resulted in a drop in demand due to disruptions in global supply chain. Stricter regulatory standards and need for vaccines and medications during the pandemic revived the market growth for TOC Analysers.



TOC-L Total Organic Analyzer
for Laboratory Applications
(An analyzer capable of measuring an extremely wide range concentrations from 4 µg/L to 30,000 mg/L, from ultra-high purity water to highly contaminated water)

The Russia-Ukraine war has caused disruption in the supply chain increasing raw material costs, thereby affecting TOC market as well.

TOC Analyzer Market in India - Present Scenario

Over 1,000 units of TOC analysers are expected to be sold in FY2023 which is nearly 200 Cr in terms of value. Nearly two thirds of the demand is for Online TOC Analysers and the remaining is for Laboratory analysers. Pharma and environmental segments share almost equally with respect to the market requirements.

TOC Analyzer Market in India - Future Forecast

The TOC analyser market is estimated to grow by CAGR : 9.57% in terms of volume (units) during FY2024-2031, from 1,185 units in FY2024 to 2,248 units in FY2031. In terms of value (INR) the market is estimated to grow by CAGR: 9.22% during FY2024-2031, from 207 Cr in FY2024 to 383.79 Cr in FY2031.

Growth Drivers are: increasing need for water quality testing, advancements in technology, increasing demand for water recycling and reuse etc.

Greener Instrument Designs

The TOC analyser market is witnessing a growing focus on sustainable and green technologies. Manufacturers are developing analysers that prioritize energy efficiency, utilize eco-friendly / recyclable materials, and reduce environmental impact. These sustainable technologies align with the broader sustainability goals of industries and regulatory bodies, aiming to minimize carbon footprint and promote environmental conservation.

Increasing field of applications and usage

Currently TOC has significant application in the production of pharmaceutical products which are subjected to stringent regulatory requirements, through monitoring Purified water (PW), Water For Injectable (WFI). Another next important application is monitoring treated wastewater before discharge, which has to meet limits on COD/BOD. Though TOC is not a parameter to be used for regulatory purposes in India, it is gaining ground to establishing factors and estimation of COD/BOD on realtime basis. Awareness is growing on the importance of water quality testing using TOC Parameter.

Some details on growing applications:

Rivers: By mapping TOC values for all the critically polluted river stretches we can control the wastewater discharge into the rivers and protect precious water resources.

Sea Water: By monitoring coastal waters, we can protect coastal belts, marine life and environment.

Lakes: By monitoring lakes, we can

- *The TOC analyzer market grew by CAGR : 7.96% in terms of volume (units) during FY2017-2022, from 661 units in FY2017 to 969 units in FY2022. In terms of value (INR) the market grew by CAGR: 7.63% during FY2017-2022, from 117.86 Cr in FY2017 to 170.15 Cr in FY2022.*
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prevent eutrophication and protect aquatic life viz., fish, prawns, crabs etc. from toxic pollutants, sewage, sullage, effluent ingress caused by rapid industrial growth.

Ground water: Determination of TOC in ground water can provide information on extent of ground water contamination by organic compounds (Landfill Leachates / Mining such as Oil exploration & extraction).

Rain Water: TOC levels of harvested rain water can determine its usage as it can mix with many pollutants from non-point sources.

Drinking Water: Monitoring TOC level to limit organics level before chlorination helps prevent formation of carcinogenic by-products.

Process Water: Monitoring TOC levels of process water viz., boiler water and cooling tower water helps in prevention of corrosion (in boilers, turbines etc.) and biofouling (of condensers, cooling towers etc.)

Waste Water: TOC monitoring is indispensable tool for Process control & Asset protection, Maintaining optimal food to microorganism ratio, Optimization of UF & RO membranes. Though TOC analysis is done for regulatory compliance, it can be used for Process control and cost reduction can be achieved.

Market players

Laboratory TOC Analysers are based on:

- High temperature Catalytic Combustion Oxidation / NDIR detection method

  OR
- Wet Chemical Oxidation NDIR detection method

Companies offering the above technologies are: Shimadzu, Beckman, GE/Suez/Veolia, Analytical Jena, Elementar, OI Analytical, Teledyne Tekmar, Skalar etc.

Online TOC Analysers Environmental market are based on:

- High temperature Catalytic Combustion Oxidation / NDIR detection method
- Wet Chemical Oxidation NDIR Detection method
- Two stage advanced oxidation & NDIR detection method Online

Several companies offering the above technologies are: Shimadzu, Hach, LAR, Horiba, Forbes, GE / Suez/Veolia

Online TOC Analysers Pure Water Pharmaceutical market are based on:

- UV –Irradiation Oxidation / Conductivity Detection method

Several companies offering the above technologies are Beckman Coulter, GE/Suez , Mettler Toledo, Membra pure, Shimadzu , etc.

Market Share in India

The top 3 companies offering Lab TOC & Online Analysers in Pharmaceutical segment are below:

Pharmaceutical

1. Lab TOC analysers

(i) Shimadzu (65%)

(ii) GE (11%)

(iii) Beckman Coulter (5%)

Balance others.

2. Online TOC analysers

Ch.Vijay Kumar founded and established Swan Environmental Pvt. Ltd. in the year 1988 to offer wide range of analytical instruments for protecting the natural resources. He formed 3 more companies viz., Swan Technical Services, Swan Biotec, Swan Scientific in the year 2016 to segment and serve in a focused manner. He is very selective in choosing a technology partner and gives utmost importance to technology based on global reference standard methods. His expertise helps in studying the customer specifications thoroughly and providing the best solution ensuring full customer satisfaction. He conducted many Seminars & Work Shops PAN India and educated the Industry on various latest and best monitoring technologies for Environment, Health & Safety (EHS). He won several awards from Shimadzu for his contributions made in spreading awareness about Importance of TOC and for his outstanding sales performance in South Asia Region. He may be contacted at : vijay@swanenviron.com.

TOC-4200 Online TOC Analyzer

(Supports monitoring TOC removal rate based on EPA regulations, useful in Wastewater treatment plants, monitoring of river water, water for use in production facilities etc.)

(i) GE (21%)

(ii) Beckman Coulter (15%)

(iii) Mettler Toledo (13%)

Balance others.

The top 3 companies offering Lab TOC & Online TOC Analysers in Environmental segment are below

Environmental

1. Lab TOC analysers

(i) Shimadzu (57%)

(ii) Analytik Jena (12%)

(iii) Elementar (8%)

Balance others

2. Online TOC analysers

(i) Shimadzu (45%)

(ii) Hach (20%)

(iii) LAR (12%)

Balance others

Shimadzu is a global leader in TOC analysers and Shimadzu in the year 1984 invented the 680°C catalytic combustion method to take care of the salt fusion issues commonly faced in high temperature catalytic combustion methods and today it is the world standard over years. Upgraded models with many advancements like space saving concepts, reduction in power consumption, eco-friendly concepts, rugged design, continuous upgrades aimed to be user friendly, updated software meeting for regulatory compliance requirements etc. are enabling Shimadzu TOC to enjoy more than 50% of market share in Lab TOC in all the segments and Online TOC in Environmental Segment. Also the new Online TOC for pure water application which is the smallest TOC launched in 2020 which meets regulatory compliance is expanding the market and is likely to increase the market dominance in near future.

USP Type 4 (Flow Through Cell) Dissolution Apparatus for Pharmaceuticals

Suhas Yewale
Associate Director-
Techno Commercial
Sotax India Private Limited
Mumbai

Dissolution testing is widely used in the pharmaceutical industry for optimization of formulation and quality control. It is useful in the pharmaceutical and biotechnology industry to formulate drug dosage forms and to develop quality control specifications for its manufacturing process: to identify the critical manufacturing variable, like the binding agent effect, mixing effects, granulation procedure, coating parameters and comparative profile studies; to assess batch-to-batch consistency of solid oral dosage forms, to support waiver for bioequivalence requirements. In the study of Bio waivers, as a surrogate for *in-vivo* studies. In the *In-vitro* *in-vivo* correlations. To comply with guidelines set in the scale up and post approval changes (SUPAC) and ICH, to select candidate formulation, to simulate food effect on bio availability, to measure the stability of the investigational product.

Dissolution is defined as the process by which a solid substance enters into a solvent to yield a solution and is controlled by the affinity between the solid substance and the solvent. Dissolution testing is an official test in the pharmacopoeia for evaluation of a variety of dosage forms (solid, semi-solid, suspension and transdermal). However, no standard method is recommended for *in-vitro* release testing of novel dosage forms such as microspheres, nanoparticles, liposomes, aerosols and drug eluting stents (DES). Developing a standardized dissolution method for these dosage forms is difficult because the release is dependent on various physico-chemical properties of the formulations, and the biological environment in which the drug release will occur. The objective of this article is to familiarize the readers with dissolution methods available or followed for testing of some of these novel dosage forms.

Dissolution testing is harmonized between United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese

> ***Dissolution testing is an official test in the pharmacopoeia for evaluation of a variety of dosage forms (solid, semi-solid, suspension and transdermal). Dissolution testing is a niche market with a high added value as it requires expertise, knowledge as well as a deep understanding and a rigorous application of the regulation guidelines***

Pharmacopoeia (JP). The general descriptions of USP apparatus 1 to 4 and their suitability, acceptance criteria of the tests are given in USP and EP. USP apparatus 1 and 2 are described as is in the JP. While USP apparatus 3 is not accepted in JP, USP apparatus 4 is described as apparatus 3 in the JP. A mastication instrument for evaluation of chewing gums is also detailed in EP. Dissolution test for transdermal systems is described in USP and EP, while there is no dissolution test specified for transdermal patches in JP.

An apparatus is not an instrument but a device which will maintain the dosage form in defined hydrodynamical and sink conditions (based on the physico-chemical properties of the API). An immediate consequence is that every dissolution instrument, containing the apparatus has to be conceived in accordance with the Pharmacopeia description in its design and in its performance. The Flow through cell method (USP Apparatus 4) for the determination of the dissolution rate / release rate is a convincing alternative to the known stirrer methods. This method is especially recommended for samples with problems involving sink conditions, for poorly soluble active substances as well as for methods that require media changes during the test. The flow through method is not only successfully used for tablets and capsules, but with dedicated flow through cells also for suppositories, fish oil capsules, powders and granulates, gels & creams as well as implants. The flow through method can solve particular sticking, floating, and sampling problems. It can be used with a complete flexibility on dissolution media volume without changing hydrodynamic conditions. Finally, the Apparatus 4 can also be used from APIs to manufacturing intermediates to final dosage forms to gather critical information helping formulation and manufacturing understanding. The flow-through cell method is therefore essential in R&D and transferable to QC. All along the 40 years of the USP4 story, new applications were developed based on the market needs. This innovative process is allowed by bringing together a complete understanding of the formulations characteristics and development as well as of the dissolution technique and find the most suitable fit. Sample cells for tablets, capsules, implants, powders, granulates, ointments, gels, creams, suspensions, microspheres, liposomes as well as lipophilic solid dosage forms e.g., suppositories are commercially available.

The cell for lipophilic dosage forms is described in the E.P. chapter 2.9.42 Dissolution test for lipophilic solid dosage forms and in the USP chapter <2040> Disintegration and Dissolution of Dietary Supplements and the USP chapter <1094> Capsules-Dissolution Testing and relative quality attributes. It is also

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described in the FDA draft guidance for Omega 3 Acid Ethyl Esters and on Isocapent Ethyl (both for quantitative capsule rupture test). This cell has been extensively used for suppositories in R&D and in QC. Due to its double chamber design, the cell for lipophilic dosage forms allows a better mixing of both aqueous and lipidic phases while maintaining the fatty excipients into the cell.

There are different dissolution media and apparatus for dissolution testing of both conventional and novel dosage forms. Because of the complex nature of some parenterals, the *in vitro* drug release test methods will be applied on a case-by-case basis rather than using a one-size-fits-all *in vitro* release test methods for drug formulations for parenteral applications.

It is an expert driven market, as dissolution testing is a niche market with a high added value as it requires expertise, knowledge as well as a deep understanding and a rigorous application of the regulation guidelines. Batches of drug products released for patient use depend on the accuracy of test results and therefore implies a strong responsibility from the perspective of the manufacturer. Good dissolution instrument manufacturers hire employees from the academia or the industry to strengthen their partnership with customers and ensure that their inner knowledge level is adequate to answer the daily customer challenges.

Auto Titrator Market in India

Dr. S.Thyagarajan
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– Titration Product Group
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Chennai

Auto Titrators are used in Titration, which is a laboratory method for determining and analyzing chemical composition of any substance, product, liquid or solutions. By Product they are segregated as Potentiometric Titrators, Karl Fischer Titrators, Coulometric Titrators, Amperometric Titrators, and Thermometric Titrators. It is widely utilized in research, quality control of drugs, excipients and other chemicals, chemical analysis, moisture analysis. Globally, development of efficient & advanced technology, rising amount of analysis carried out by various industries & product developments and the growing healthcare industry are the prime growth drivers of the titrators market. In addition, an increase in adoption of titrators for application in new industrial verticals, and emerging economies such as China, India and others, will create new opportunities for the titrators market. Geographically, Europe dominated the titrators market, followed by North America. European and North America market together account for more than 70% of the market size. Asia Pacific is projected to have the fastest growth, owing to a rapidly growing healthcare industry, rise in industrial sector, investment in research and development, and growing pharmaceutical, and personal care applications in developing nations such as China and India in this region. Among all the applications, the chemical industry has the highest market share in the titrators market.

Industry demand in India

Auto titrators find applications in various industries and laboratories for tasks such as quality control, research and development, and environmental analysis. Some factors that may influence the auto titrator market in India include:

Pharmaceutical Industry

The pharmaceutical sector in India is a significant consumer of auto titrators. These instruments are used for pharmaceutical analysis, including the determination of drug purity, assay, and dissolution testing. Most of the pharma industry uses instruments which are FDA Compliant (21 CFR Part 11).

Chemical Industry

The chemical manufacturing sector employs auto titrators for quality control, product development, and process optimization. Industries such as petrochemicals, specialty chemicals, and agrochemicals use these instruments extensively.

Food & Beverage Industry

Auto titrators are used for food and beverage analysis, including acidity and alkalinity measurements, as well as the determination of additives and preservatives. Increased regulations from FSSAI will see an increase in the auto titrator business in this industry.

Environmental Monitoring

Environmental agencies, research institutions, and laboratories use auto titrators to analyze water and soil samples, measure pollutants, and assess environmental quality.

Academic and Research Institutions

Educational institutions and research laboratories in India use auto titrators for teaching purposes and various research applications.

Petrochemical Industries

In Petrochemical industries, titrators play a vital role and they are used in analysis of raw materials (crude oil) and finished products (lube oil, fuel etc.).

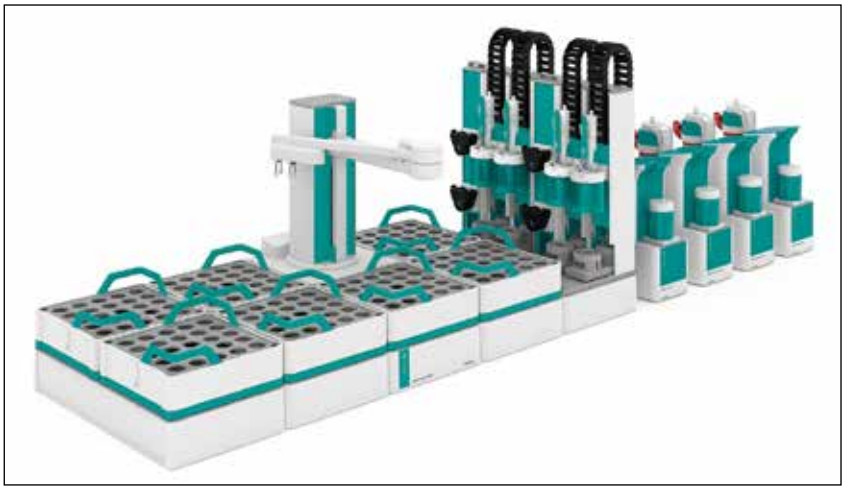
The market for auto titrators in India is likely to grow as these industries continue to expand and emphasize quality control, compliance with regulations, and efficient analytical processes. The automation and

precision offered by auto titrators make them valuable tools for laboratories and industries requiring accurate and reproducible titration results.

Auto Titrator Business in India

The Indian market for auto titrators is competitive, with both domestic and international manufacturers and distributors operating in the country. Leading global companies in the analytical instrument industry often have a presence in India. The total auto titrator (both Potentiometric and Karl Fischer) numbers that are sold in India is around 800 to 1,000 units of imported instruments and the total business value is around USD 14M in 2022. The business is expected to grow at a CAGR of around 5.1% between 2022 - 2028. The domestic manufacturers also sell around 800 - 1000 units of variety of titrators. It is difficult to estimate the market size and turnover due to too many localised manufacturers who dominate their local market. Of late few of the Indian manufacturers have also started exporting to nearby countries and in African market.

The automation sales at this moment along with titrators is very low but poised to increase with cost of personnel in India to increase substantially in near future and also due to increased requirement of accuracy and repeatability of the results acquired.

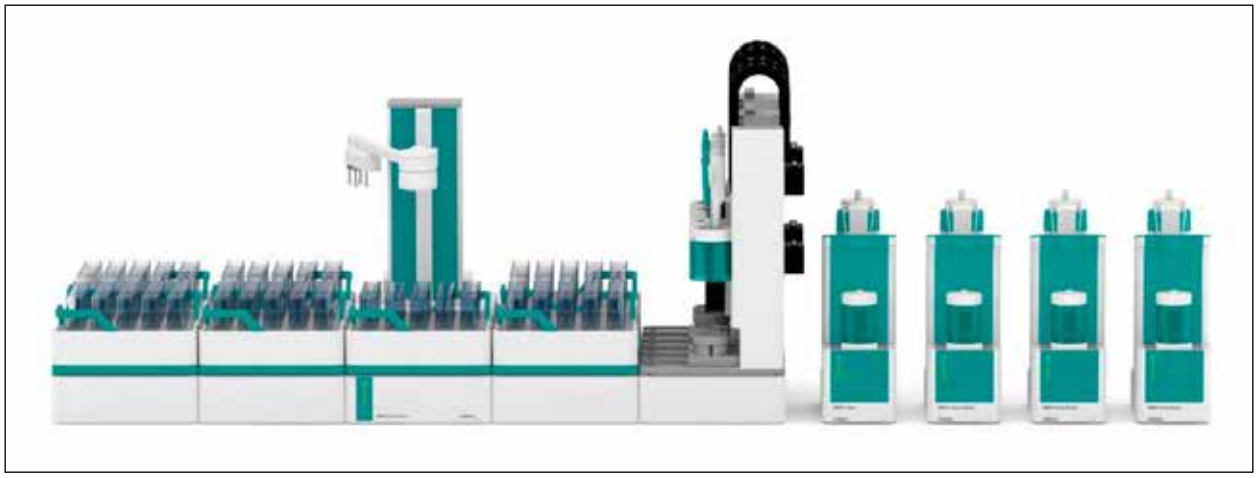


Major Brands of auto titrator in Indian market:

- Metrohm AG
- Mettler Toledo
- LabIndia
- Spectralab
- Xylem Inc.
- Hanna Instruments.

The companies in the auto titrator business adhere to regulatory standards, especially it is required in industries like pharmaceuticals and food, where stringent quality control measures are essential. The market for auto titrators in India will experience growth as industries continue to expand, regulations become more stringent, and there is an increasing emphasis on quality control and environmental compliance. The auto titrator business is a dynamic and evolving field that plays a crucial role in various scientific and industrial applications. Companies operating in this space need to adapt to changing technologies and customer needs, to remain competitive and contribute to advancements in analytical chemistry and quality control.

Dr.S.Thyagarajan completed under graduation and post-graduation in chemistry from Madras University and further completed PhD from Bharathidasan University and Post graduate diploma in management from LIBA. He started his career in 2003 with Orchid Chemicals and Pharmaceuticals as an analytical chemist. After two years of experience in pharmaceutical industry, he joined Metrohm India Private Limited, as an application chemist. During this period he worked as an application specialist for Titration, Voltammetry, Ion chromatography and Flash chromatography instruments. After 8 years of experience in Application Lab, he moved into sales as a Territory Manager and later joined the Marketing Team in 2015. Currently he is working as a Product manager for Titration product group, providing technical and marketing support to the sales team.



> ***Auto Titrators are segregated as Potentiometric Titrators, Karl Fischer Titrators, Coulometric Titrators, Amperometric Titrators, and Thermometric Titrations. They are widely utilized in research, quality control of drugs, excipients and other chemicals, dissolution tests, chemical analysis, moisture analysis, acidity/ alkalinity measurements, analysis of pollutants in environment, additives/preservatives in foods etc.***

Advancements in Titration

Due to the increased workload in the auto titrations in pharmaceutical, chemical and food industries, these customers are now looking for automation solutions like sample handling systems that can load and unload samples automatically. Sample changers or robotic arms can transport samples from sample containers to the titration system, reducing the need for manual sample preparation. Some of the applications require time consuming sample preparation steps, which can now be completely automated with the help of certain accessories that can be connected to the auto titrators. Automation reduces the workload on laboratory personnel, minimizes the risk of human error, and ensures consistent and reliable results. Moreover, automation allows laboratories to handle a higher sample throughput, making it particularly beneficial in high-demand settings.

Advances in technology, including more precise dosing pumps and sensors, have improved the precision and accuracy of auto titrations. This is crucial for industries with stringent quality control requirements, such as pharmaceuticals and food. Manufacturers have developed user-friendly software interfaces for auto titrators, making them easier to set up, program, and operate. Most of the customers are now looking for data management without any human intervention and have integrated their instrument data using LIMS.

Auto Titrator Market – The Road Ahead

Even though titration is an old method of analysis, the global market for titrators is predicted to develop steadily. The vast volume of analysis carried out by numerous industries, as well as product developments, are significant elements to the increase. The predicted rise of the product in the market is due to increased demand in numerous sectors such as pharmaceutical, chemical, food & beverage, and textile, to name a few. The use of titration as a preferred method of water and chemical analysis in these industries is expected to propel the titrators market forward. The device's applicability is also extensive, which is expected to be a driving element in the product's market expansion. The shift in the trend towards parallel or dual titrators with automation is expected to contribute to the product's growth in the market. Overall, the auto titrator business in India looks promising and shows good potential.

Imaged Capillary Isoelectric Focusing (icIEF) - Growth in the Indian Market

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In the development of biotherapeutics, genetic variations, and post-translational modifications give each molecule a 'personality'. Understanding these unique characteristics drives the development, manufacturability, and analytical methods used to monitor and control the quality attributes and testing requirements. Imaged capillary isoelectric focusing (icIEF) is the industry's gold standard for protein charge heterogeneous analysis due to its excellent sensitivity, high throughput, outstanding repeatability, and has been widely used in the biopharma industry.

Development in technology

Although imaged capillary isoelectric focusing (icIEF) has received wide recognition for protein heterogeneity, the biopharma industry is in an era of great change in biopharmaceutical analysis with a thirst for new solutions to address big challenges in protein characterization, including complex protein characterization, new mass spectrometry (MS) tandem technology and preparation of protein charge variants. Recently, four review articles highlight and evaluate the important developments of icIEF technology, especially from Advanced Electrophoresis Solutions (AES), including high-resolution ampholytes, MS online, and fractionation of protein charge variants in the biopharma industry.

- *K. Maráková, M. Opetová, R. Tomašovský, Journal of Separation Science, Capillary electrophoresis-mass spectrometry for intact protein analysis: Pharmaceutical and biomedical applications (2018–March 2023), 2023, 46, 2300244.*
- *S. Hartung, R. Minkner, M. Olabi, H. Watzig, Trends in Analytical Chemistry, Performance of capillary electrophoresis instruments e State of the art and outlook, 2023, 163, 117056.*
- *Barry L. Karger, Trends in Analytical Analysis, Perspectives on capillary electrophoresis, 2023, 167, 117215.*

• *F. Krebs, H. Zagst, M. Stein et al, Electrophoresis, Strategies for capillary electrophoresis: Method development and validation for pharmaceutical and biological applications, 2023, 44 (17-18), 1279.*

Prof. Karger in his review insights into the perspectives on capillary electrophoresis in the Trends in Analytical Chemistry by citing 37 latest publications with important influences, and highlights that 'Isoelectric focusing, as we have noted, is an important protein characterization method and is widely used in CE. However, the coupling of CE and MS has been limited in part because of interference by the carrier ampholytes. There is a clear need for online coupling of cIEF and MS as isolation of specific cIEF peaks for MS analysis can take days to complete. There is active work going on direct cIEF-MS coupling and even MS coupling to imaged cIEF, generally using low levels of ampholytes. We can anticipate increasing use of cIEF-MS systems.' Without any doubt, icIEF-MS technology makes the protein heterogeneity characterization more 'elegant' - straightforward, sensitive, high-throughput, and high data consistent!

Recently, there have been great changes in the biopharma industry, including stricter regulations and the strong demands on icIEF new solutions and workflow from the scientists in protein chemistry. This in turn has inspired capillary electrophoresis providers to develop cutting-edge icIEF technology and provide the most suitable products and technique solutions to give support for the CMC strategy and entire lifetime cycle in the biopharma industry. It is worth mentioning that AES has evolved traditional icIEF with just UV detection to comprehensive characterization by critical reagent-driven icIEF-UV, icIEF-MS, and icIEF fractionation as below breakthroughs, which newly defines the icIEF solution and workflow of protein heterogeneous

> ***Imaged capillary isoelectric focusing (icIEF), a technology platform developed based on Whole Column Imaging Detection (WCID) has become indispensable to the biopharma industry due to its high analytical throughput, ease-of-use, fast method development, and excellent reproducibility. The technology has compatibility with the traditional electrospray ionization (ESI) interface for several commercial MS instruments offering straightforward workflows for icIEF-MS.***

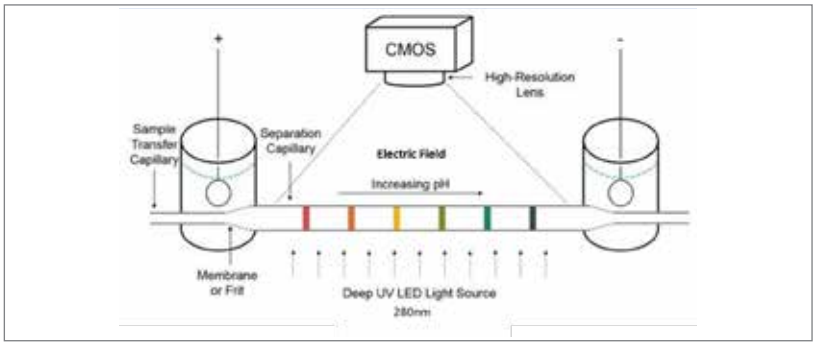


Fig. 1: icIEF with WCID for highly efficient protein separation

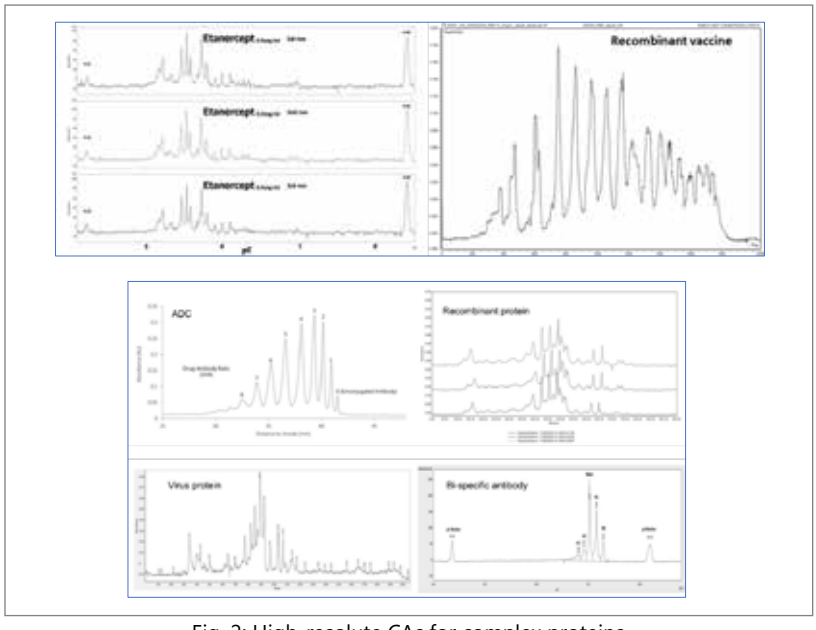
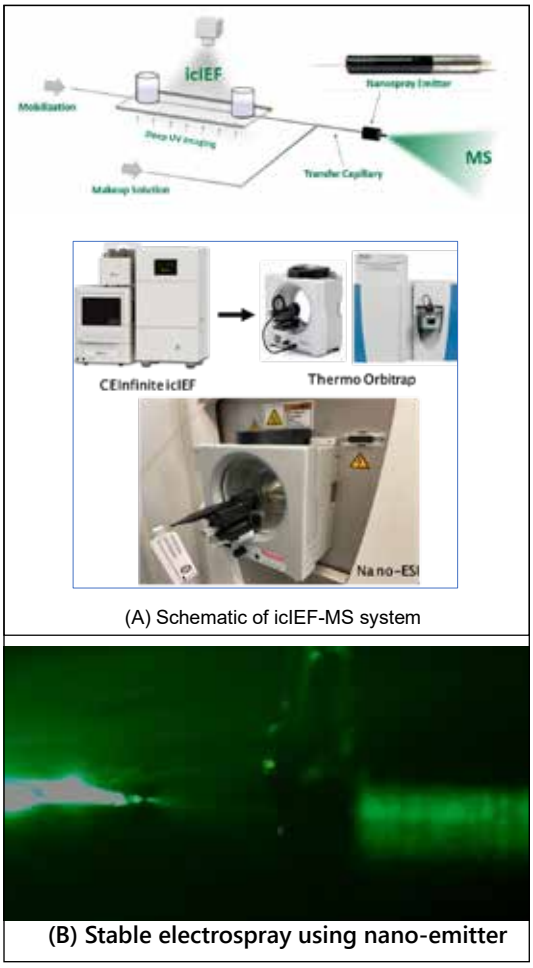


Fig. 2: High-resolute CAs for complex proteins

characterization in the biopharma industry as the latest publication below.

• *Analytical Chemistry, Mass Spectrometry-Based Charge Heterogeneity*



(A) Schematic of icIEF-MS system

(B) Stable electrospray using nano-emitter

Fig. 3: Schematic of icIEF-MS system with the Nano-spray Emitter connecting the interface.

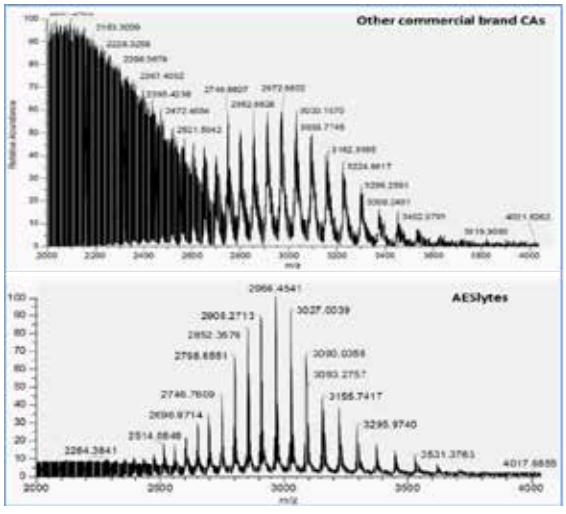


Fig. 4: Customized CAs for icIEF-MS with low background

Characterization of Therapeutic mAbs with Imaged Capillary Isoelectric Focusing and Ion-Exchange Chromatography as Separation Techniques, 2023, 95, 2548-2560.

- *Analytical Methods, Fractionation and online mass spectrometry based on imaged capillary isoelectric focusing (icIEF) for characterizing charge heterogeneity of therapeutic antibody (Cover featured article), 2023, 15, 411-418.*
- *Analytical Biochemistry, Cutting-edge mass spectrometry strategy based on imaged capillary isoelectric focusing (icIEF) technology for characterizing charge heterogeneity of monoclonal antibody, 2023, 660, 114961-114972.*
- *Journal of Pharmaceutical and Biomedical Analysis, Imaged capillary isoelectric focusing (icIEF) tandem high resolution mass spectrometry for charged heterogeneity of protein drugs in biopharmaceutical discovery, 2023, 115178-115189.*
- *Separation Science plus, High-efficient characterization of complex protein drugs by imaged capillary isoelectric focusing with high-resolution ampholytes, 2023, 6 (2), 2200142-2200153.*
- *Rapid Communications in Mass Spectrometry, Integrating ultra-high-performance liquid chromatography tandem mass spectrometry and imaged capillary isoelectric for in-depth characterization of complex fusion proteins, 2023, 37, e9484-9492.*
- *Separation Science plus, Imaged capillary isoelectric focusing employing fluorocarbon and methylcellulose coated fused silica capillary for characterization of charge heterogeneity of protein biopharmaceuticals (Cover featured article), 2023, 6 (5), 2200160-2200169.*
- *Analytical Biochemistry, Imaged capillary isoelectric focusing tandem high-resolution mass spectrometry using nano electrospray ionization (ESI) for protein heterogeneity characterization, 2023, 680, 115312.*

icIEF technology is a regulated method in biopharma development, quality control, and manufacture release in the biopharma industry. However, for the long term, icIEF-UV has been the single mode, and what frustrated the biopharma industry is how to extend icIEF capability to MS online coupling and fractionation purpose

with more straightforward strategy. Otherwise, icIEF analysis cannot build an effective bridge with traditional HPLC-MS and IEX-MS, especially for extremely complex proteins with complicated PTMs including recombinant vaccines and fusion proteins. In addition, routine carrier ampholytes cannot solve complex protein samples with satisfactory resolution in icIEF separation. The developed icIEF workflow from AES demonstrates an essential role of high-resolution carrier ampholytes in the efficient icIEF separation of extremely complex protein systems and exhibited an important contribution of icIEF-MS online to rapidly fingerprinting the complex heterogeneity of recombinant vaccine. Moreover, icIEF fractionation greatly simplified the complexity of protein samples, which allowed it to carry out the in-depth and more accurate characterization of collected fractions by HPLC-MS and IEX-MS. icIEF-MS online and icIEF fractionation can give fresh vitalities to the heterogeneity characterization of complex protein samples.

High-resolution Carrier Ampholyte for icIEF for Complex Proteins

Besides traditional high-performance liquid chromatography (HPLC) and ion exchange chromatography (IEX), capillary electrophoresis (CE) has become an essential technology for the charge variant characterization of mAbs and other complex proteins. As illustrated in Fig. 1, imaged capillary isoelectric focusing (icIEF) is a technology platform developed based on Whole Column Imaging Detection (WCID). The ampholyte in the capillary forms a pH gradient by applying an electric field, and the proteins are distributed along the pH gradient in the capillary according to their respective isoelectric points (pI), thereby realizing the separation of proteins. This method of capillary isoelectric focusing enables extremely efficient separation of proteins. A detection system consisting of deep UV LEDs and imaging sensor is used for monitoring the separation on the capillary column in real time. Currently, imaged capillary isoelectric focusing (icIEF) has become indispensable to the biopharma industry due to its high analytical throughput, ease-of-use, fast method development, and excellent reproducibility.

A carrier ampholyte (CA) is a molecule containing both acid and base functionality that is critical for imaged capillary isoelectric focusing (icIEF). The quality of an icIEF separation for protein charge variants' characterization is highly dependent on attributes of the CAs used including baseline signal, linearity of the pH gradient, pI discrimination, and consistency between manufactured lots. AESlytes commercialized by AES are a high-resolution carrier ampholyte series that have been developed for the

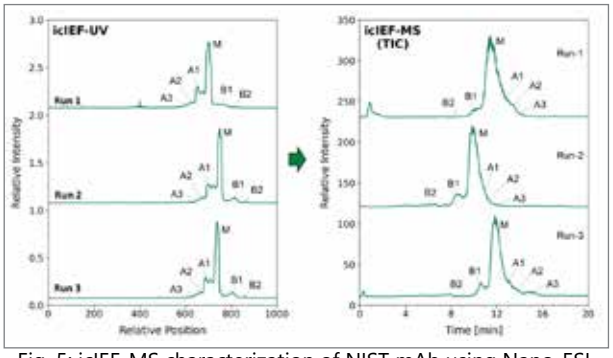


Fig. 5: icIEF-MS characterization of NIST mAb using Nano-ESI.

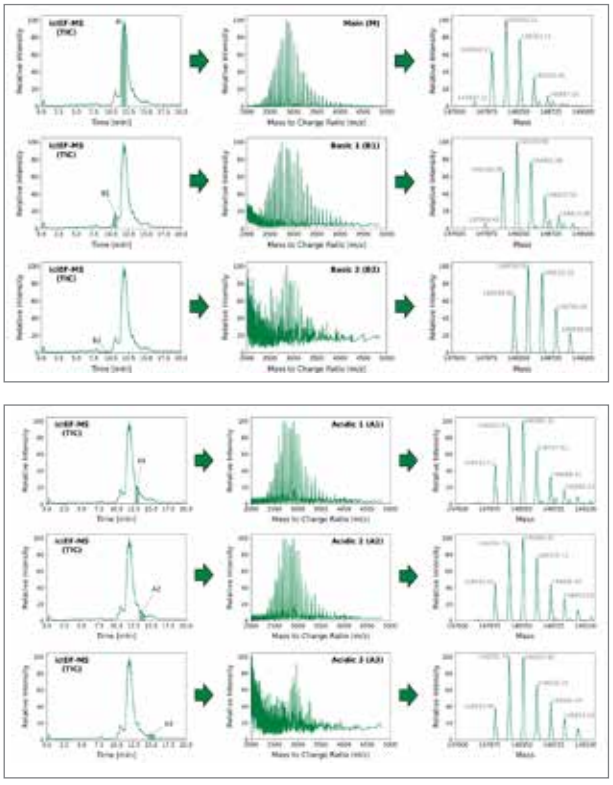


Fig. 6: icIEF-MS deconvolution of NIST mAb (1mg/ml, n=3) using the nano-ESI.

high-resolution and selective characterization of diverse and complex protein drugs including diverse fusion proteins, antibody-drug-conjugate (ADC), bi-specific antibody (BsAb), viral protein, recombinant vaccine, and AVV as shown in Fig. 2. While routine commercial ampholytes usually cannot solve such challenges, AESlytes demonstrate a reduction in baseline noise and distinguishably increased consistency between lots as compared to other commercial ampholytes. AESlytes are utilized for the icIEF separation of complex proteins and biosimilars with excellent repeatability.

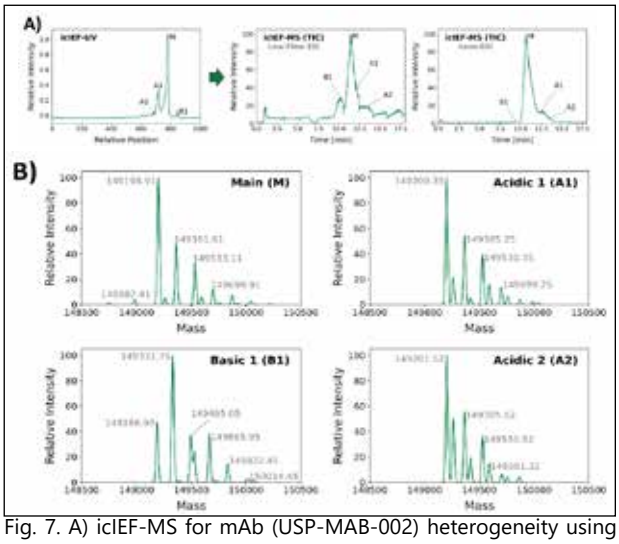


Fig. 7. A) icIEF-MS for mAb (USP-MAB-002) heterogeneity using nano-ESI; B) The deconvolution of the icIEF-MS profile for nano-ESI.

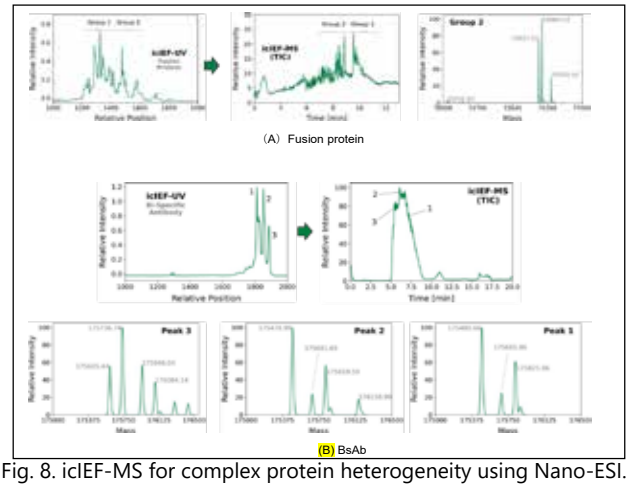


Fig. 8. icIEF-MS for complex protein heterogeneity using Nano-ESI.

It is demonstrated that high-resolution carrier ampholytes as critical reagents play an essential role in high-performance icIEF and icIEF-MS analysis that routinely commercial CAs cannot achieve, especially for extremely complex protein drugs. The features of AESlytes outlined here will be far-reaching in the design and quality control of complex protein drugs.

icIEF-MS for Accurate Protein Heterogeneous Characterization

A pressure-driven mobilization technique along with a patented transfer capillary has been developed to maintain the integrity of the icIEF profile for improved resolution and high sensitivity. Proprietary carrier ampholytes and capillary coatings, along with a makeup solution prior to the MS interface, have effectively mitigated concerns related to background interference and volatility. Overall, it has compatibility with the traditional electrospray ionization (ESI) interface for several commercial MS instruments. Additionally, it has been reported that the robust charge heterogeneity characterization of nine therapeutic mAbs demonstrated improved sensitivity, lower carryover effect, and higher resolution when compared to strong cation exchange (SCX)-MS. In addition, the nano-pressure mobility AES developed allows for excellent stability and straightforward workflow of icIEF-MS, which overcomes the poor repeatability and tedious workflow resulting from traditional chemical mobilization in icIEF technology.

Fig. 3A illustrates the configuration and workflow of the icIEF-MS with a nano-ESI including coated capillary separation cartridge that includes a quartz union (works as a micro-tee) to connect the make-up solution and transfer capillary to ESI, nano-flow pump for the mobilization of focused protein bands, and the microliter interface (50µm ID nano-emitter constructed by fused silica capillary) with built-in platinum electrode designed and a beveled-tip (50o slope angle). The beveled emitter geometry maintains stable electrospray over a wide flow rate range (Fig. 3B).

As indicated in Fig. 4, it is demonstrated that high-resolution AESLyte ampholytes play a critical role in improved selectivity during the icIEF-MS analysis and our comprehensive selection of pH range ampholytes can be used to customize an icIEF-MS protocol for optimal performance. As compared to routine CAs providers, AESLyte CAs demonstrate a much lower MS background, which greatly contributes to highly sensitive icIEF-MS analysis of proteins. The standard NIST mAb was used to evaluate the performance of icIEF-MS with the nano-ESI interfaces. As shown in Fig.5, 1 mg/mL NIST mAb demonstrated excellent sensitivity and repeatability with the nano-ESI, while the five charge variants with subtle pI discrimination could be resolved using the nano-ESI. Fig.6 illustrated icIEF-MS deconvolution of NIST mAb' charge variants (1mg/ml, n=3).

icIEF-HRMS were used to characterize the heterogeneity of mAb (USP-MAB-002, 1mg/ml). As seen from Fig. 7A, the nano-ESI revealed the main component and its three charge variants (A1, A2 and B) with satisfactory sensitivity and resolution. The deconvoluted MS information is then shown in Fig 2-7B, and even basic variant can be detected at low concentrations due to excellent sensitivity of the nano-ESI. Compared to the low-flow ESI shown in Fig. 2-7A, the nano-ESI demonstrated less TIC baseline fluctuation and less background interference with better peak shape. This enables the identification of the two acidic variants (A1 and A2) with more certainty and contributes to accurate semi-quantitation of charge variants based on peak area percentage.

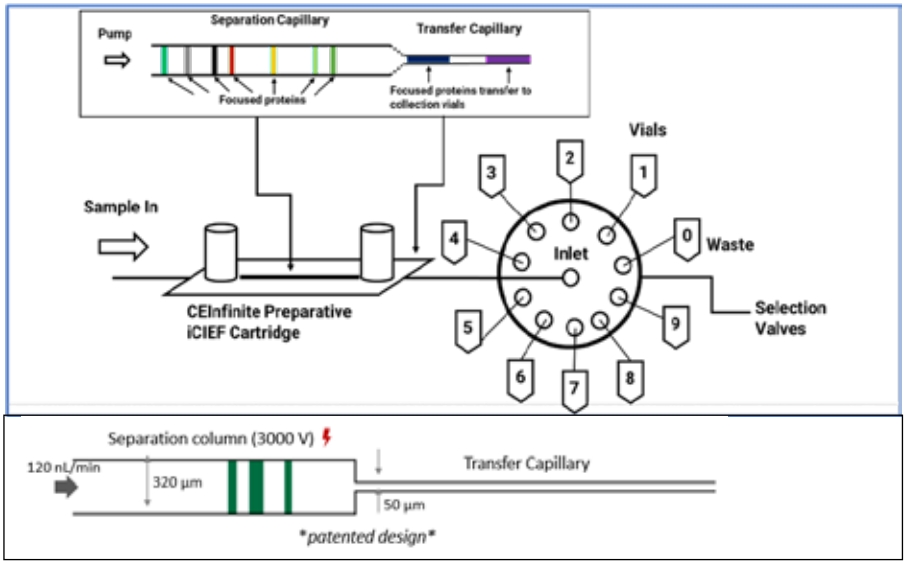


Fig. 9 Configurations of fraction collections by preparative icIEF

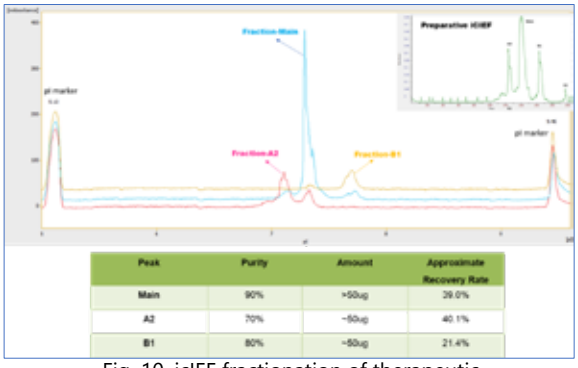


Fig. 10. icIEF fractionation of therapeutic mAb charge variants

Recently, complex proteins including antibody-drug conjugates (ADCs), bi-specific Abs (BsAb), and fusion proteins have regained the special attention of scientists due to their unique therapeutic effects. Few applications of characterizing such complex proteins by CE-MS have been reported. Especially for fusion proteins or recombinant proteins with extreme components, both HPLC-MS and CE-MS are very challenging with very weak signals of MS due to complex and high glycations so the deglycosylation process of protein samples is critical for MS detection in our recent study. However, the type of fusion protein with low glycations can be directly analyzed by mass spectrometry, the icIEF-HRMS platform with nano-ESI was applied to complex proteins to demonstrate its wide applicability. As shown in Fig. 8A, the Fusion Protein-EX with low glycations demonstrated a fairly complex mapping of protein components with two peak groups and molecular weights ranging from 60-100K for all detected proteins. A typical deconvoluted MS from Group-2 is shown in Fig. 8A. Furthermore, the characterization of a BsAb is also on display in Fig. 8B, and it contains three major charge variants with rather high pI values greater than 9.5 and the molecular weight around 175K. The sensitivity was outstanding and the MS TIC demonstrated the discrimination of three variants even though their pI differences are rather subtle.

icIEF-Fractionation for In-depth Protein Heterogeneity

icIEF technology has been proven to be robust for the characterization of protein charge heterogeneity due to its high-resolution pI discrimination and high throughput. Although offline fraction collection technologies including isoelectric focusing (IEF), ion exchange chromatography (IEX), and free flow electrophoresis (FFE) have been widely utilized for preparing protein charge variants, there are a few applications of icIEF as a separation technique for the auto-fractionation for protein charge heterogeneity. Since 2018, AES has developed a platform of icIEF fractionation with high-efficient workflow for protein charge variants. The identity of collected fractions can be in-depth characterized by LC-MS and IEX-MS at the levels of intact protein and peptide mapping. Moreover, the platform of icIEF fractionation can be rapidly and flexibly switched to icIEF-UV icIEF-MS operation models just by changing customized capillary separation cartridges without drastically altering instrument configuration. The whole workflow of icIEF-based profiling, fractionation, and MS online coupling for protein heterogeneity can be achieved on a CEInfinite instrument with straightforward workflow, excellent reliability, and high accuracy, thus providing comprehensive solutions for in-depth protein

heterogeneity characterization. The most importantly, icIEF fractionation technology can warrant the data consistency during the whole process of protein drug development and establish a robust bridge between icIEF-UV profiling and intact protein identification, which can be addressed by traditional off-line fractionation platforms.

Commercial icIEF preparative technology from AES can realize the separation, preparation, and collection of high-purity, heterogeneous, charged protein products as illustrated in Fig 9. Based on a straightforward icIEF method, minimum method optimization is required to test a new biopharmaceutical product. After protein focusing is completed, water serves as a mobilization solvent, flowing from the syringe pump at 120 nL/min flowing rate to drive the focused protein bands out of the separation capillary for fraction collection while maintaining the high voltage. By the continuous migration of hydroxide ions from the cathodic side and protons from the anodic side of the separation capillary, the charge variant peaks in the separation capillary remain focused under the electric field.

As illustrated in Fig. 10, the two major acidic and basic charge variants of a therapeutic monoclonal antibody were collected using preparative icIEF fractionation after the protein focusing on the separation capillary. The identity of the fractions was confirmed by LC-MS at intact protein level and the results were consistent with those using icIEF-MS online coupling. The whole workflow of icIEF-based profiling, fractionation, and MS online coupling for protein heterogeneity is straightforward, reliable, and accurate, thus providing comprehensive solutions for in-depth protein heterogeneity characterization.

The developed icIEF fractionation workflow has been used for complex proteins with excellent results including recovery, preparation capacity, fraction purity, and throughput, including fusion protein, recombinant vaccine, and ADC.

icIEF fractionation and online icIEF-MS were developed for charge variant analysis after analytical icIEF-UV profiling. The established hybrid platform was successfully utilized for in-depth charge variant characterization of a therapeutic antibody. The fractions of a main protein component with its two major charge variants were collected for following LC-MS analysis at the intact protein level. Meanwhile, icIEF-MS coupling was performed for rapid identification of protein heterogeneity. The whole workflows of icIEF-based fractionation and MS online detection for protein heterogeneity are straightforward, reliable, and accurate, which can provide comprehensive and cutting-edge technologies for protein drug quality control (QC) monitoring, online MS detection for rapid fingerprinting intact proteins and HPLC-MS in-depth characterization of collected fractions.

The way ahead-mass spectrometry strategy on complex protein with comprehensive separation techniques to characterize complex heterogeneity

Due to extreme complexity of recombinant vaccine, fusion protein, bi-specific Ab and ADC, a workflow containing comprehensive separation techniques coupled to high-resolution MS is essential for dissecting its complicated heterogeneity. Traditional HPLC-MS and HPLC-MS/MS were utilized for characterization of complex proteins at the levels of intact protein analysis and peptide mapping with PTMs identification. The cutting-edge technologies including icIEF-MS online and icIEF fractionation integrating IEX-MS were explored to investigate their applicability in in-depth characterization of complex protein compositions with high-throughput, straightforward methodology and excellent sensitivity. The integrated workflow underlines the outstanding importance of comprehensive platforms based on MS technology and the essential contributions from innovative icIEF-MS and preparative icIEF in the development of complex protein systems.

icIEF technology is a regulated method in biopharma development, quality control, and manufacture release in the biopharma industry. However, for the long term, icIEF-UV has been the single mode and what frustrates the biopharma industry is how to extend icIEF capability to MS online coupling and fractionation purposes with a more straightforward strategy. Otherwise, icIEF analysis cannot build an effective bridge with traditional HPLC-MS and IEX-MS, especially for extremely complex proteins with complicated PTMs including recombinant vaccine and fusion protein. In addition, routine carrier ampholytes cannot solve complex protein samples with satisfactory resolution in icIEF separation. It is demonstrated that an essential role of high-resolution carrier ampholytes in high-efficient icIEF separation of extremely complex protein system and exhibited an important contribution of icIEF-MS online to rapidly fingerprint the complex heterogeneity of recombinant vaccine. Moreover, icIEF fractionation greatly simplifies the complexity of protein samples, which allows it to carry out in-depth and more accurate characterization of collected fractions by HPLC-MS and IEX-MS. icIEF-MS online and icIEF fractionation can give fresh vitalities to the heterogeneity characterization of complex protein samples.

Laboratory 4.0: Navigating New Trends and Challenges in Lab Digitization

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Innovation is the driving force behind progress, and the laboratory industry is no exception to this rule. As we journey further into the digital age, laboratories are undergoing a transformation like never before. Laboratory 4.0, a term that summarizes the latest trends and challenges in lab digitization, is reshaping the way scientists and analysts conduct research and development (R&D) while striving for innovation in fundamental research.

The Why Behind Lab Digitization: In today's laboratories, scientists and analysts demand safe and controlled spaces, free from contaminants, where high-throughput technologies can streamline R&D processes and enhance innovation. Digitization and automation play a pivotal role in achieving these objectives, leading to improved speed, cost control, and overall efficiency of tests. By automating repetitive tasks, they minimize manual errors and reduce variability, ensuring better quality and compliance. These digital advancements empower laboratories to adopt a risk-based approach, optimizing testing volume, tools, and methods, thereby enabling faster problem resolution. The result? Quality control becomes faster, more agile, more reliable, more compliant, and more efficient.

Continuous Monitoring for Enhanced Efficiency: One of the critical aspects of lab digitization is the continuous monitoring of lab equipment. This monitoring serves to prevent malfunctions, reduce downtime, improve efficiency, and ensure product safety. Insights gained from equipment monitoring aid in optimizing equipment usage, preventing excessive energy consumption due to equipment overuse, and enhancing overall energy efficiency through effective schedule management.

Data Analytics: The Game Changer Data analytics is at the forefront of the laboratory 4.0 movement. Data acts as the fuel for unlocking the full potential of digital technology. More data, especially accurate data, is crucial for achieving better solutions. However, managing the increasing volume of digital data can be a daunting task. Regardless of the type of laboratory, whether it be for discovery, research, or industrial purposes, the accuracy of results and insights is paramount for driving scientific discoveries and creating new products.

Quality Assurance and Control Quality assurance and quality control are principal throughout the development of pharmaceutical products, ensuring safety and compliance before reaching consumers. Digitalization has the potential to significantly enhance these processes. Traditionally, pharmaceutical labs have collected vast amounts of data without harnessing its full potential. However, with the arrival of digitalization and IoT-powered

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> ***A Comprehensive Solution for maintaining acceptable levels within lab environments, such as temperature, humidity, VOC and CO_2/O_2 levels, common services like gases and energy monitoring is essential for successful laboratory operations. IoT-powered integrated laboratory monitoring solutions, exemplified by Kewaunee's Lab Asimo, have emerged as a comprehensive solution for these critical needs.***

integrated laboratory monitoring solutions, labs can communicate and share data, automatically identifying potential quality control issues. The application of new technology is inevitable for productivity, accessibility, security, and sustainability.

Industry 4.0 and Pharma-Manufacturing Labs The emerging technologies that define Industry 4.0, including connectivity, advanced analytics, robotics, and automation, are poised to revolutionize every aspect of pharma-manufacturing labs. This transformation enables the R&D industry to achieve sustainability goals and tap into the wealth of data for actionable insights, resulting in better solutions and enhanced financial outcomes.

A Comprehensive Solution for Lab Monitoring In maintaining acceptable levels within lab environments, such as temperature, humidity, and VOC and CO2/O2 levels, monitoring is essential. Additionally, monitoring of common services like gases and energy is crucial. IoT-powered integrated laboratory monitoring solutions, exemplified by Kewaunee's Lab Asimo, have emerged as a comprehensive solution for these critical needs.

Lab Asimo: Realizing the dream Kewaunee's Lab Asimo offers a platform that addresses the challenges of Laboratory 4.0. It provides a complete solution for monitoring and reporting in regulated and critical environments, including a unique Lab Safety Index, revolutionizing fume hood performance and utilization reporting. Lab Asimo transforms raw data into valuable insights, enabling non-intrusive monitoring and preventive maintenance. With quality control systems in place, laboratories can operate more efficiently, ensuring accurate production and reproducible results.

In conclusion, the laboratory industry is undergoing a profound transformation driven by digitalization and Laboratory 4.0. As laboratories embrace these trends and tackle the associated challenges, they are poised to achieve new heights of innovation, quality, and efficiency, ultimately shaping a brighter future for scientific discovery and product development.

Ensuring Safe Drinking Water: Urgent Need for Comprehensive Testing

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India, a country blessed with abundant water resources, relies on various sources for providing clean drinking water to its citizens. Public Drinking Water (PDW) and Family Household Tap Connections (FHTC) serve as lifelines to millions, but ensuring the safety of this water is a pressing concern. Recent data reveals a staggering reality: out of the 18,91,026 water sources in India, a whopping 16,77,544 (90%) have yet to be tested for chemical contamination, a situation demanding immediate attention and action.

As per the latest information available at Jalshakti board[1], these numbers are not static. They are in constant flux, increasing every single day. The urgency to test these sources cannot be overstated, given the vital role water plays in public health. The lack of comprehensive testing poses a significant risk, as it compromises the health and well-being of millions who depend on these sources for their daily water needs.

Taking Action for Clean Water: India's Path to a Healthier Tomorrow

One of the critical challenges faced in this regard is the need for higher throughput and accuracy in the analysis process. The current system demands an overhaul to ensure quicker and more precise testing of samples. By improving the turnaround time of incoming samples, more water sources can be assessed daily with higher precision. This enhancement is crucial in addressing the existing gap between the vast number of water sources and the limited testing facilities available.

Comprehensive testing is essential to identify potential chemical contaminants, ensuring that the water supply meets the necessary safety standards. This includes analyzing water samples for pollutants, heavy metals, and other harmful substances that could pose severe health risks, especially in the long term.

Comprehensive testing is essential to identify potential chemical contaminants, ensuring that the water supply meets the necessary safety standards. This includes analyzing water samples for pollutants, heavy metals, and other harmful substances that could pose severe health risks, especially in the long term.

Citizens, policymakers, and stakeholders alike must collaborate to prioritize the testing of these water sources. Public awareness campaigns are necessary to inform people about the importance of clean water and to encourage communities to participate actively in water testing initiatives.

Furthermore, investments in research and technology are pivotal to developing advanced testing methods that are not only accurate but also swift. Harnessing innovative solutions can significantly expedite the testing process, allowing for a more extensive coverage of water sources.

Bridging the Gap: Advancing Water Testing for a Healthier Future

In conclusion, ensuring the safety of drinking water in India demands immediate and concerted efforts. The increasing number of untested water sources is a cause for concern, but it also presents an opportunity for proactive intervention. By investing in advanced testing technologies, raising public awareness, and fostering collaboration between government bodies, communities, and the private sector, India can take a significant step towards providing safe and clean drinking water for all its citizens. The time to act is now, for a healthier and more secure future for all.

SmartChem: Empowering India's Water Safety Revolution

Introducing SmartChem, a groundbreaking automated colorimetric system, promises a transformative solution. SmartChem revolutionizes water testing by offering higher throughput and unparalleled accuracy. Its complete automation drastically reduces the turnaround time for sample analysis, allowing for more samples to be tested daily with precision. In the face of rising demand, SmartChem's efficiency fills the gap between the need for water testing and limited facilities. This technology ensures reliable and swift detection of chemical contaminants, providing essential data for decision-making. By embracing SmartChem, India can guarantee safe drinking water for millions, marking a significant leap in ensuring public health and well-being.

Web Reference

1. https://ejalshakti.gov.in/WQMIS/Report/source_testing_lab_ftk

Akshay Charegaonkar is a dynamic and accomplished professional, currently serving as the Director of Anchrom Enterprises, a leading provider of analytical instruments and solutions since 1978 Akshay graduated with a degree in Chemistry from the Rochester Institute of Technology in New York. During his academic journey, he honed his skills and knowledge in the field of chemistry. Since 2010 he works at Anchrom as the Director of Business Development and strategic projects, where he plays a crucial role in expanding the company's customer base and strengthening its market presence. Associations: (1) Chairman of Executive Committee of the International HPTLC Association based in Switzerland since 2021 (2) Hon. Secretary of the Indian Analytical Instruments Associat ion based in Mumbai since 2022

The Importance of Chemical Safety in Industries

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There is very common saying that "सर सलामत तो पगड़ी हजार" and no wonder if we have to do anything worthwhile or achieve anything substantial, the body is the vehicle by which the goals / objectives will eventually be achieved.

Chemical safety is one such critical area where there is huge risk of being exposed to different hazards with chemicals, solvents, KSM, compounds, catalysts, it's handling, operating conditions, storage, movement, chemical runaway reactions, dust explosion, pilot operation and scale up activities .

With the increasing complexity of chemicals, new chemicals, noble chemistry, continuous process, process intensification, new catalyst development, green chemistry initiatives are introduced regularly into various industries, and the risks involved become increasingly difficult to control and manage safely and efficiently . The pressure of profitability and customer satisfaction is all time high with time to market race and plants are operating under difficult conditions with different batch sizes, bigger volumes, different campaign, faster turnaround time to cope up with the demand and supply and align the manufacturing activities accordingly.

> ***In chemical safety, the term "hazard" refers to the inherent hazardous properties of a chemical or a chemical operation, while "risk" means the likelihood of the hazardous properties of a chemical or the hazards of a chemical operation causing harm to people and the severity of that harm.***
>
> ***Risk = Probability X Severity***

What is chemical accident?

A chemical accident is defined as a harmful release, dispersal, discharge, or escape of a toxic substance or mixture into the environment that causes damage to human health or the natural environment and affects a wide range of living organisms in the affected area or along the transport route of the hazardous material (e.g., air, soil, groundwater, surface water, etc.).

In the year 1984, India experienced the world's worst chemical (Industrial) disaster, the Infamous "Bhopal Gas Tragedy," which was the most devastating chemical accident in history, killing thousands of people due to the accidental release of the toxic gas Methyl Iso Cyanate (MIC) from storage tanks .

Different types of chemical hazards:

Chemical industries use large amounts of chemical products in the production of different kinds of goods, from food to medicine, cosmetics, paints, and many more things that we use every day in our daily lives. The main purpose of chemical industries is to produce chemical raw materials and intermediate chemicals, which they

sell to other industries for producing finished goods.

Chemicals used in industry often have to undergo processes such as extraction, purification, concentration, mixing with other materials, and so on before they are delivered for use in products or services (e g., cleaning agents) .

Hazards and risks associated with Chemical operation

In chemical safety, the term "hazard" refers to the inherent hazardous properties of a chemical or a chemical operation, while "risk" means the likelihood of the hazardous properties of a chemical or the hazards of a chemical operation causing harm to people and the severity of that harm.

Risk = Probability x Severity

A chemical change involves in chemical reactions such as decomposition, combination, neutralisation, oxidation and reduction, etc. This results in transformation of the starting materials (known as reactants) to other substances with different chemical structures and properties (known as products). In physical change, physical forms of the materials change to other forms by operations such as heating, grinding, ultrasonic vibration, dissolution, dilution, etc. Physical forms include gas, vapour, fumes, aerosol, liquid, airborne particulate, dust cloud, powders and solids.

Some of the most common chemical hazards are as below.

Inorganic chemicals include acids, salts, minerals, and others. It can be a corrosive agent, an irritant, and also a flammable agent. Hazardous inorganic chemicals cause burns and corrosive injuries, as well as asthma, respiratory problems, and cancer.

Organic chemicals are substances that are naturally occurring or produced by living organisms. These chemicals include alcohols, aldehydes, ethers, ketones, and so on. They can cause skin irritations, asthma and respiratory problems, eye injuries, cancer and even death. Chemical hazards may be produced by a human or by a non-living object or system. These chemicals include metals, gases, and liquids as a chemical can exist in different states.

Crucial Checks during Risk assessment of a Chemical operation

1. What are the chemicals involved & process?

2. Are chemical reactions involved? Is there any side reaction? What are the reactants, products and by-products?

3. What are the hazardous properties of the chemicals?

4. What are the physical forms of the chemicals? Are the chemicals easily inhaled? Are flammable/explosive mixtures formed? Characteristics of the operation.

5. Is heat generated and it is exothermic reactions? Is there any danger of localized heating or superheating? Does the heat cause vaporisation of the reaction mixture ?

6. Are gaseous products or vapours formed and gas is evolved during the process ?

7. Will the heat or gases/vapours generated create pressure in the container? Are the pressure-relief facilities of the container good enough to allow release of excessive pressure? Can the container withstand the excessive pressure?

8. How does temperature affect the reaction? Does the reaction need to be initiated by rise in temperature? Does the reaction once initiated auto-accelerate so that it may be out of control?

9. Are the reaction, reactants or products sensitive to light? What are the reactions and products

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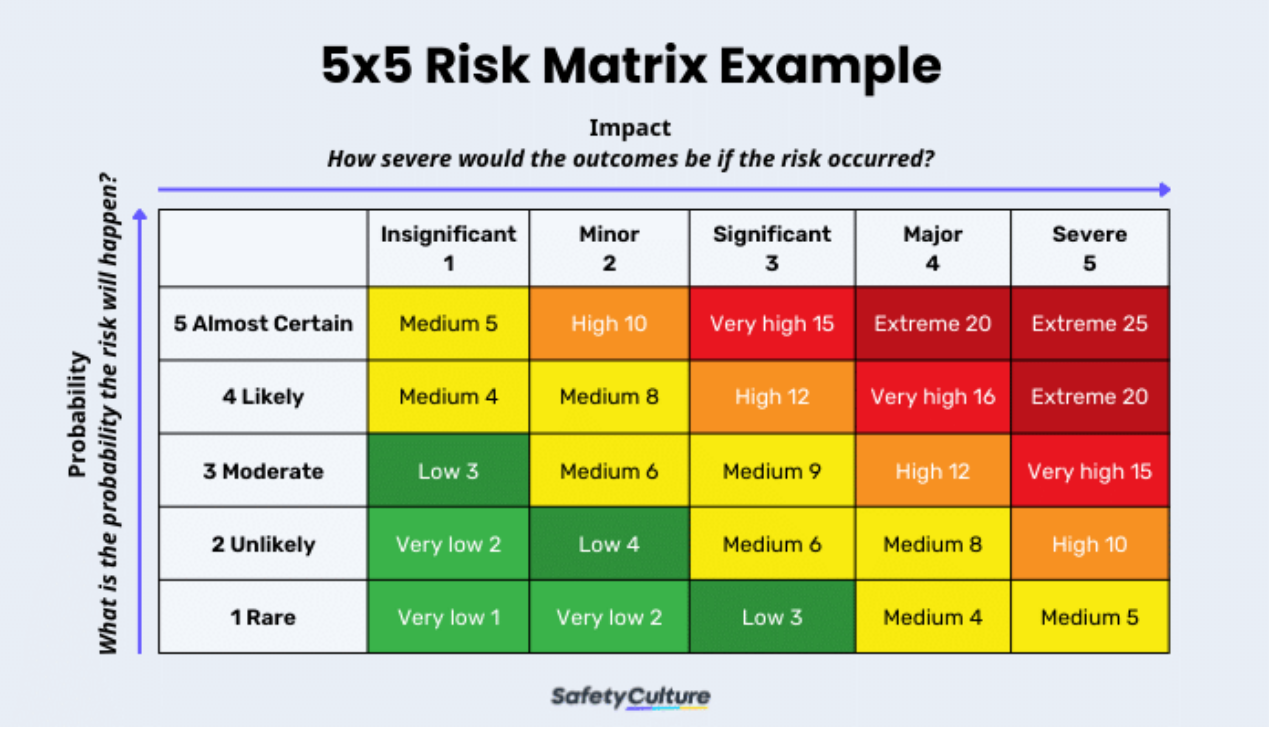


induced by light? Are they hazardous ?

10. Are the reactants or products sensitive to heat, air or water? What are the reactions and products induced by heat, air or water? Are they hazardous?

Chemical Hazards

The chemical industries have their own set of hazards, in addition to the general dangers posed by other industries such as mining, petroleum refining, and so on, which endanger life, property, or the environment. The chemicals are extremely flammable, explosive, corrosive, toxic, reactive, and poisonous substances that can be hazardous if not handled properly and safely.

There are various types of chemical accidents, among which 'explosion' is a serious one and can create havoc if the reactions are not studied well within the controlled conditions in the lab and rate of heat generated or gas evolved is not quantified properly for runaway reactions. It is defined as an event which involves the rapid release of energy due to some form of ignition accompanied by an increase in the volume of air, gases, liquids, or solids (chemical) or other forms of energy (mechanical , electric spark , friction , Impact etc .). Such an event may also involve a combination of these three effects, depending on the circumstances of the incident. This is one of the most dangerous chemical hazards and fatal.

Chemical hazards can be caused by numerous sources, some of them as below .

1) Leaks from storage tanks containing highly flammable chemicals
2) Unstable chemical compound explosions
3) Fires involving combustible materials
4) Unintentional emissions from industrial processes
5) Explosive gas combustion
6) Combustion of natural gas
7) Combustion of organic chemicals
8) Ignition of stored explosives
9) Toxic and/or hazardous substance combustion
10) Incendiaries

Where to find hazards of chemicals

Material Safety Data Sheets (MSDS) , labels , handbooks, manual should be referenced to understand the hazards that chemicals pose to workers. All workers should be aware of the types of chemicals they are exposed to, and company management should ensure that they have adequate controls implemented to prevent people from being exposed to the health and physical hazards of chemicals.

Chemical review

The management must evaluate the hazards of the chemicals they produce, import, use, store, or handle. Assessing the risks associated with chemical hazards

allows the management to understand the controls needed to prevent injury, illness, environmental contamination, or property damage.

Follow the Hierarchy of Controls

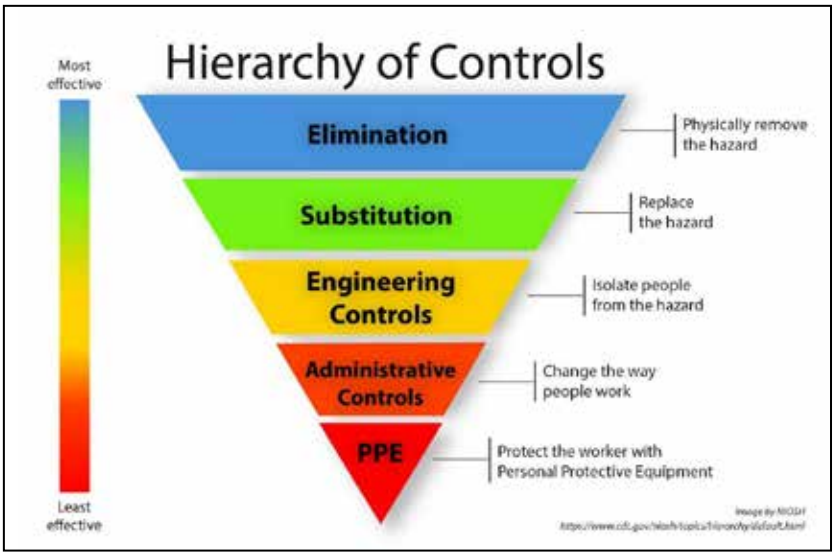
Companies should always follow the Hierarchy of Controls when managing workplace hazards associated with chemicals. The most effective control is eliminating the chemical hazard; however complete elimination is usually not possible since multiple chemicals are used in many manufacturing processes hence keeping the safety data and implementation of PHA (Process Hazard assessment) is the important .

The subsequent most effective control is substitution. After chemist analyses which specific chemicals they use, they should attempt to find a safer alternative. For example, if a company uses a methylene chloride-based paint stripper, they should switch it for a safer option.

If a safer chemical alternative cannot be found, engineering controls should be next to reduce chemical hazards. Engineering controls require a physical change in the workplace, decreasing the potential for exposure. In conjunction with engineering controls, administrative and work practice controls should be used. As a last resort, PPE, such as respirators, should prevent employees from being exposed to chemicals. In addition, other PPE should be used to minimize exposure to chemicals, such as compatible gloves, aprons, safety glasses, goggles, or face shields.

Labelling, SDS, and training

Other chemical safety tips in the workplace include labelling chemicals and ensuring that SDS are available for each chemical used, stored, or managed. Employees must be trained in the chemicals they are using, including the associated hazards, how to use chemicals, and how to protect themselves from exposure.



Safe storage

The company should ensure that they are storing chemicals safely. For example, chemicals should be kept away from direct sunlight, heat sources, and exit routes. In addition, only compatible chemicals should be stored together.

Chemical Safety Program

The company management should have a written chemical safety program and communicated to all employees exposed to potential chemical hazards. The chemical safety program should detail the types of chemicals in the workplace, their hazards, controls established, how and when employees to be informed and trained, how chemicals should be labelled, and what to do in the event of a chemical emergency such as if a chemical alarm is triggered.

When companies use the Hierarchy of Controls and other best practices to control chemical hazards, the risk of chemical exposure will be minimized, resulting in fewer injuries and illnesses, increased productivity and morale, improved communication and emergency response, and will ultimately save the company's money.

Health and Physical Hazards

Chemical hazards and toxic substances present a broad array of health and physical hazards that employers need to be cognizant of.

Health hazards

For health hazards, chemicals can be carcinogens (capable of causing cancer), mutagens (causes genetic mutation), respiratory sensitizers, respiratory tract irritants, and can cause reproductive toxicity, target organ toxicity, and aspiration toxicity. In addition, chemicals can be skin sensitizers and cause skin and eye damage, irritation, corrosion, or burns.

Physical hazards

For physical hazards, chemicals can be flammable, corrosive, pyrophoric (capable of igniting spontaneously when exposed to air), self-heating, self-reactive, or explosive. These characteristics can cause chemical leaks, fires, or explosions that injure or kill workers or cause severe property or environmental damage. The effect of a toxic chemical on a worker's body can be acute or chronic.

Chronic or long-term effects may take months or years to surface and usually are permanent. Chronic effects are generally caused by regular exposure to a harmful chemical over time. An example of a chronic effect would be the latency period of asbestos exposure. It takes 10-40 years of asbestos exposure to cause health issues such as lung cancer, asbestosis, or mesothelioma.

Way forward on Chemical Management and Safety In The Workplace

• On Employee and worker health: Implement proper chemical management which significantly reduces the risk of occupational illnesses, injuries, and exposures.

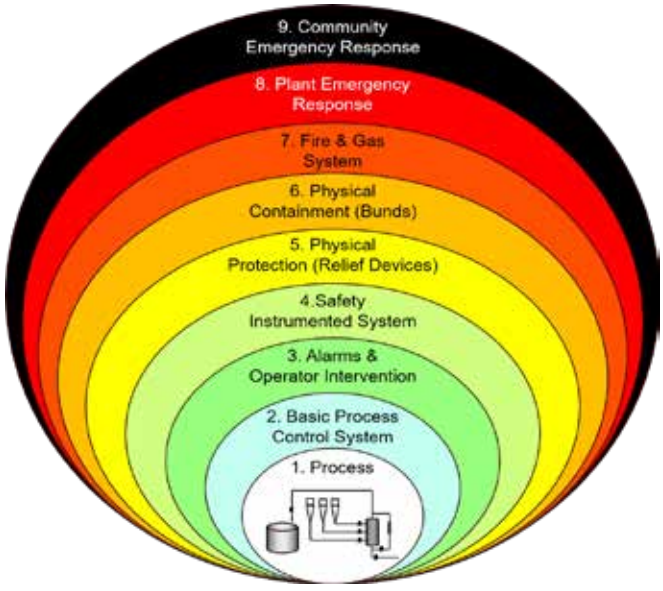
• On Costs: By preventing accidents and injuries, businesses will avoid medical expenses, worker compensation claims, and potential legal liabilities. Additionally, minimizing chemical waste through proper storage, handling, and disposal practices reduces the need for costly clean up procedures and environmental remediation.

• On Performance & efficiency: When chemical management protocols are in place, employees can work more efficiently and confidently. They understand the hazards associated with the chemicals they handle, have the necessary training and resources to mitigate risks, and can focus on their tasks without concerns about their safety.

• On Maintenance & Compliance: Chemical management will ensures that businesses comply with the ever-evolving regulations and laws governing the use, storage, transportation, and disposal of chemicals. It demonstrates commitment to sustainability by implementing eco-friendly practices.

To help ensure safe and healthful workplaces, OSHA advocates the Process Safety Management of Highly Hazardous Chemicals standard (29 CFR 1910.119), which contains requirements for the management of hazards associated with processes using highly hazardous chemicals.

As hazardous chemical releases pose a significant threat to living beings and ecosystem, the key provision of Process Safety Management (PSM) and Process Hazard Analysis (PHA), Layers of Protection Analysis (LOPA) must be made with careful review of what could go wrong and what safeguards must be implemented to prevent releases of hazardous chemicals into the environment in order to help making our planet a safer & greener place .



Beyond Speed and Capacity – Laboratory Centrifuges

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Centrifuge is a ubiquitous instrument used for separation or sedimentation of suspended components in liquids. While centrifuges are used widely in various fields, in life sciences this technique is commonly used for preparation, isolation and purification. Applications in Life science laboratories include blood component separation, isolation of biomolecules such as protein and nucleic acids, harvesting of cultured microbes or cells. Purification of low molecular weight homogenous components such as virus, proteins, and polymers are the other applications that needs high or ultra-speed centrifuges.

Technological advances along with the need for low volumes and higher speeds have led to the development and diversification of centrifuges into micro, multi-purpose, and ultracentrifuges to cater to relevant applications and user requirement. Need for the temperature control and the technology behind the refrigeration have significantly evolved with the criticality of the sample integrity in their preparatory phase. With the quantum of samples processed and the vessel formats required to meet defined volumes, the need for flexible rotors with adapters to accommodate multiple formats have gained significant attention from the users.

The major factors that propel the growth of the laboratory centrifuge market include improving public health care, increased educational and research activities in the field of life sciences, agriculture & biotechnology, rise in prevalence and incidence of disease that demands for new drugs and therapeutic product developments in the pharma/biopharma, increase in private & public healthcare investment.

> ***Centrifuges as per intended use are classified into general-purpose centrifuges, clinical centrifuges, preclinical centrifuges, and preparative ultracentrifuges. Based on the size and construction type they are broadly segmented into benchtop and floor-standing centrifuges.***

The global laboratory centrifuge market is segmented based on product, rotor design, intended use, application, end user, and geography. Based on product, the market is bifurcated into equipment and accessories. The equipment though commonly defined based on its maximum capacity in terms of tubes or volumes and the maximum speed or 'g' force it can attain, the need for the rotors is always based on the workflow or user applications. The choice of swinging bucket rotor, fixed angle rotors, vertical rotors, continuous rotors etc. are available. Most manufacturers also offer multiple adapters that fit into every rotor to make it more flexible. Ultimately the equipment, rotor and adapters are configured by user based on their applications and laboratory needs.

Centrifuges as per intended use are classified into general-purpose centrifuges, clinical centrifuges, preclinical centrifuges, and preparative ultracentrifuges. Based on the size and construction type they are broadly segmented into benchtop and floor-standing centrifuges. Benchtop centrifuges are cost-effective, versatile, easy-to-use, compact in size to fit

the lab bench space and considerably lighter in weight. Based on the temperature control requirement they are available either as refrigerated or non-refrigerated models.

Benchtop centrifuges

The benchtop centrifuges segment accounts for the largest market share nearly 80% in 2020[1]. This segment offers versatility, convenience, and cost-effective solutions besides the advantage to accommodate within small and compact laboratory space. Among the benchtop centrifuges are general-purpose centrifuges, microcentrifuges, small clinical centrifuges, cell washers, and high-speed centrifuges. Used both in research and clinical laboratories, they majorly cover applications such as microfiltration, sedimentation, and small volume pelleting. Further, these benchtop centrifuges are classified as microcentrifuges and multipurpose centrifuges based on the vessel formats, rotor, and speeds they can achieve. Microcentrifuges generally support the conical tube formats for volumes from 0.2 mL to 50 mL in a fixed angle rotor. while the multipurpose benchtop centrifuges support multiple formats such as conical tubes, vials, microtiter plates, deep well plates and bottles for volumes ranging from 0.2 mL to 1 litre or more.

Floor standing centrifuges

Floor standing centrifuges predominantly are used in high-capacity sample processing labs or for applications that require longer duration with continuous operation. Floor-standing high-speed centrifuges, ultracentrifuges, and blood-bag centrifuges require higher stability due to their higher tolerance for speed and volumes. These are more relevant in preparatory and scale-up processes like manufacturing segment. Manufacturers of diagnostic kits, vaccines, recombinant proteins, industrial enzymes etc. are the key users of these products. High speed centrifuges are preferred for the downstream process, isolation, purification, and concentration of the product of interest in bioprocess applications for the pharma and Biopharma segment. These centrifuges offer the advantage of higher volumes so that the batch sizes are reduced. Availability of continuous flow rotor option in these high-speed centrifuges offer an advantage over the need of bottles.

Ultracentrifuges take a significant share by value and are used for isolation of cell organelles, proteins, lipoproteins, exosomes, RNA, DNA, nanoparticles, and virus particles. Density gradient separations are the most performed method in preparative ultracentrifuges and purification of biomolecules of lower molecular weight. Ultracentrifuges offer users an enhanced set of features to ensure safety; like self-locking rotors, non-contact imbalance detection and Rotor Life Management etc.

Accessories: Rotors, adapters, and consumables

Application, number of tubes, fill volume and speed are imminent to choose the right centrifuge while the choice of fixed angle or swinging bucket rotor depends on the sample type. Fixed angle rotor accounts for the largest share in the market as it is attributed for wide range of applications in life science, molecular biology, and protein research. Fixed angle rotors with containers positioned at 28 – 45 degrees from the axis can generate higher g-forces and facilitate shorter sedimentation time. They are mostly used with benchtop and floor standing centrifuges in wide range of volumes from 0.2 mL tubes to 1.5 L bottles.

Swinging bucket rotor are widely used to isolate cells and functional proteins at a lower speed avoiding structural damage during the process. Unlike fixed angle rotor these consist moving part thus generally run at low speeds and lower g-forces. These rotors offer versatility, increased capacity, and adaptation to several vessel formats.

Current Trend

Covid-19 transformed the diagnostic landscape from classic serological to nucleic acid based molecular testing wherein the need for high-speed micro centrifuges increased several folds for sample preparation step. Post-Covid, molecular diagnostics across hospitals declined but the established laboratories are navigating to adapt diagnosis of other microbial pathogens and genetic markers. Emergence of personalized medicine with genome sequencing techniques both in research and clinical diagnosis are adopting methods towards complete profiling of individual to predisposition to lifestyle diseases. Evolving tools of molecular methods such as qPCR, dPCR, NGS etc require high quality samples and hence the demand for high performance centrifuges stay steady.

Though safety, capacity, flexibility, size and ease of use are the primary features consistently upgraded to meet quality expectations, the current trend highly considers sustainability features such as green refrigerants, environment friendly cooling agents, noise cancelling, low energy consuming systems over low-cost alternatives.

Market Drivers

Growing investment in higher education, research and healthcare has increased the need for laboratory equipment. Increasing incidence of pandemic, prevalence of chronic and lifestyle diseases too has triggered the need for new prognostic and diagnostic methods. This scenario has increased the demand for labs to equip themselves with high quality equipment including centrifuges.

India Laboratory Centrifuge Market Synopsis

The laboratory centrifuge market in India is expected to witness significant growth. This can be attributed to increasing demand from various end-use industries such as biotechnology, pharmaceuticals, food & beverages, and chemicals.

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Additionally, rising research & development activities in the healthcare sector is also fuelling the growth of this market. Furthermore, factors like growing urbanization and technological advancements are also augmenting the market growth.

According to the India Brand Equity Foundation (IBEF), India is the largest provider of generic drugs globally. Moreover, the India pharmaceutical sector supplied over 50% of the global demand for various vaccines and pharmaceutical products by volume. The Indian Economic Survey too shows that the domestic pharmaceutical market is expected to grow three-fold in the next decade.

India has also shown significant growth in the CROs market. This growth can be attributed to the increasing focus of companies on outsourcing research to India due to the availability of highly skilled techno-competent and low-cost workforce. The country is also the fastest growing hub for clinical trials ensuring the growth of associated market, such as hospitals, diagnostic laboratories, medical colleges, and research institutions.

These factors indicate significant growth in the pharmaceutical industry, which would, in turn promote the growth of the laboratory centrifuges market in the next 5 – 10 years an estimated CAGR of 6.7% growth for centrifuges in this segment.

Additionally, the growth of the Indian market for laboratory centrifuges is driven by the rapidly growing population; high incidence & prevalence of infectious disease such as AIDS, TB, Cholera etc, increasing market availability of a comprehensive range of advanced molecular diagnostics assays and techniques for disease diagnosis. This fact is also augmented by the increasing healthcare expenditure allocated by central and state governments from improving infrastructure to providing quality diagnosis and treatment to the public. Growing health care insurance too is a major factor in increasing public access to the advanced healthcare services.

The diagnostic sector in India is one of the faster growing services in the country. The domestic diagnostic industry is projected to grow at a CAGR of nearly 10% over the next five years. Growth will be primarily driven due to changes in demographics, a rise in lifestyle diseases, affordability to the advanced treatment and high-income levels across all categories of society. The diagnostic sector mainly includes hospitals with labs (37%), standalone labs (47%) and diagnostic chains (16%), out of which almost 58% are diagnostic pathology centres (Source: Edelweiss Professional Investor Research).

Type	2021	2022	2023	2024	2025	2026	CAGR (2021-2026)
Multipurpose Centrifuges	15.47	16.26	17.27	18.42	19.73	21.23	6.5%
Microcentrifuges	12.98	13.54	14.33	15.18	16.19	17.34	6.0%
Ultracentrifuges	7.68	8.12	8.54	8.99	9.52	10.12	5.7%
Minicentrifuges	5.54	5.74	6.00	6.28	6.62	7.01	4.8%
Other Centrifuges	2.71	2.80	2.92	3.04	3.19	3.37	4.5%
Total	44.38	46.46	49.06	51.91	55.25	59.07	5.0%

Source: World Health Organization (WHO), International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Centers for Disease Control and Prevention (CDC), National Center for Biotechnology Information (NCBI), US Department of Health and Human Services (HHS), Annual Reports, SEC Filings, Investor Presentations, Press Releases, Expert Interviews, and MarketsandMarkets Analysis

Key Players in the Market

Centrifuge being a common laboratory instrument, there are both regional and global players vying for the market shares; however there are also segment and application-based profiles to meet their ultimate goals. Global brands include Eppendorf SE, Thermo Fisher Scientific Inc., Sigma, Beckman Coulter Inc., Hettich Instruments Ltd., wherein regional Indian manufacturers such as Remi, Neuation etc have significant market shares.

Reference

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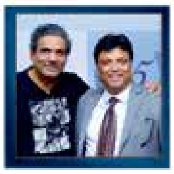

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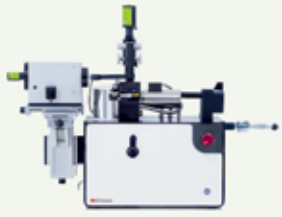

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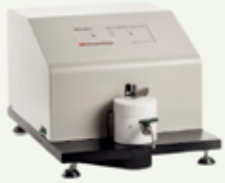

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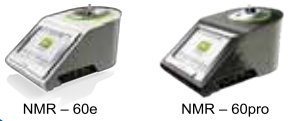

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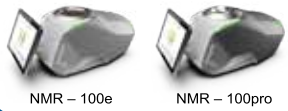

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Established over 25 years ago, PEAK Scientific is a world leading gas generator manufacturer who supplies & supports laboratory-grade gas generators. PEAK provide highly reliable and robust solutions, validated & approved for many analytical laboratory applications, including LC-MS (Liquid Chromatography – Mass Spectrometry) and GC (Gas Chromatography). PEAK's range of nitrogen, hydrogen and zero air gas generators can be used across a breadth of industries including pharmaceuticals, bio-pharmaceutical, Food, forensics, and environmental testing. PEAK gas generators incorporate a combination of leading innovative technologies to produce high purity laboratory gas. These components include PEM cell for hydrogen, membrane or PSA for nitrogen and catalytic chambers for zero air.

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At both full flow operation (24 hours per day, 7 days per week) and under typical usage (5 days per week, 12hrs per day), Peak's generators produced 20% less carbon emissions, making Peak's gas generators the more environmentally friendly choice for your lab.

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With a gas generator, your gas will be generated on-demand with consistent levels of purity for the best results without any waste.

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With over 80,000 generators worldwide in the last 25 years, you can trust PEAK to help you find a solution that aligns with your lab's needs.

Peak Scientific Instruments (I) Pvt. Ltd.,
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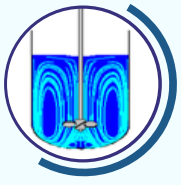

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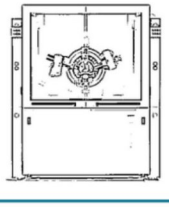
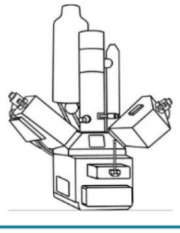
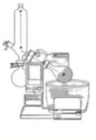

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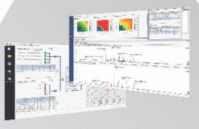
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