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“New biopharma modalities -peptides, oligo, mRNA, cell and gene therapy, ADCs, and bispecifics - will drive the analytical markets”

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Shailendra Chavan, a Sales Director Chemistries and Supplies Division at Agilent Technologies, has over two decades of experience from previous roles at Agilent Technologies. He holds a MSc in Chemistry from University of Mumbai. With a robust skill set that includes LC- MS, Gas Chromatography, Mass Spectrometry, Chromatography, Analytical Chemistry and more, he contributes valuable insights to the analytical industry. In an interaction with BioSpectrum he sheds light on the market trends in the Biosuppliers segment and discusses some of the emerging trends that is projected to change the future course of the laboratory and analytical instrument industry in India and globally.

How do you perceive the current market trends for laboratory and analytical instruments/equipment in India and abroad? What are the major challenges you face in the industry, particularly regarding the production and distribution of laboratory and analytical instruments/equipment?

The analytical instrument market in India for biopharma is growing. This growth can be attributed to several factors, including the increased investment by pharmaceutical companies in large molecules to broaden their product pipelines, as well as the rise of Contract Development and Manufacturing Organisations (CDMOs). Large molecules, due to their complexity, require thorough characterisation, aiding in understanding the efficacy of drugs. Additionally, there is a growing demand for highly reliable data that meets international standards.

Globally, the market is expanding, especially in affluent countries that heavily invest in complex biologics and various modalities. The reputable stature of Indian pharmaceutical companies is garnering global attention, leading to increased

engagement with Indian multinational companies.

However, several challenges are being encountered. For instance, in terms of cost of development and complexity. To adapt to new trends, and advancements, and ensure market sustainability, significant investments are required in developing new instruments or workflows. This entails substantial costs, which may be prohibitive for some customers at present.

Supply chain challenges are also being faced. With increasing demand for instruments, raw materials and components need to be sourced from various countries. Disruptions in the supply chain due to geopolitical issues can impact production timelines and costs.

The market is highly competitive, with each player striving to innovate for a competitive advantage. Thus, keeping pace with this trend necessitates investment in research and development.

The growing complexity of analysis for large molecules requires skilled scientists to design workflows and analyse data. Companies must invest in developing these skills among their employees and provide customer training on the use of these instruments.

Could you highlight some of the new technological developments that have significantly impacted the sector recently?

Some of the recent advancements that have really changed the face of the laboratory equipment and analytical instrument sector include Automation, Process Analytical Technology (PAT), Miniaturisation, AI Integration, Multi-Attribute Monitoring (MAM), and Digitalisation/Data Management.

Automation: To cope with the large number of samples in drug discovery and other processes, automation and robotics have become essential. These tools enhance productivity and accuracy, particularly in sample preparation.

Process Analytical Technology (PAT): With advancements in biomanufacturing and bioprocesses, there is a growing need to analyse samples in real time. Techniques for automatically withdrawing samples in-line and analysing them for critical quality attributes (CQAs) have gained prominence, enabling quicker adjustments to processes.

Miniaturisation: Due to space constraints and rising costs, there is a demand for smaller instruments. Agilent, for example, has made strides in this area with instruments like FTIR, Vaya Raman, Ultivo, and Intuvo, which optimise space utilisation.

AI Integration: Artificial Intelligence (AI) and Machine Learning (ML) are being integrated into analytical instruments to enhance data analysis and interpretation. This integration supports pattern identification, outcome prediction, and the optimisation of experimental conditions.

Multi-Attribute Monitoring (MAM): The MAM approach has become popular for comprehensively characterising monoclonal antibody (mAb) CQAs. This method offers significant savings in analysis time and cost compared to traditional methods.

Digitalisation/Data Management: With the generation of copious amounts of data in research and quality control, there is a growing demand for enhanced connectivity and efficient data management. Scientific Data Management Systems (SDMS), Electronic Lab Notebooks (ELNs), and Laboratory Information Management Systems (LIMS) are increasingly being adopted to streamline workflows and ensure smooth operations in modern laboratories.

Furthermore, there is a need to provide complete workflows for upcoming applications in various analysis areas. Agilent, as a leader in the field, continuously develops new workflows to meet regulatory requirements and provide customers with trusted answers. Our capable team of scientists supports customers in utilising the latest Agilent platforms from our Centre of Excellence.

How do you assess the growth prospects of the Indian market, especially for laboratory and analytical instruments/equipment?

The Indian market for laboratory and analytical instruments is steadily growing. Agilent, for instance, has a significant number of its products like chromatography and mass spectrometry already installed in the country.

As new regulations demand highly sensitive and advanced technology products, there's a growing replacement market. Many organisations are looking to upgrade their current infrastructure to the latest platforms. Additionally, as markets expand into new sectors like semiconductor testing, there will be a high demand for niche technologies such as atomic spectroscopy.

Regulations in fields like food, pharmaceuticals, and biopharmaceuticals are continuously evolving. This evolution is expected to drive further market expansion in India over the next few years.

Could you give us an overview of your company's portfolio and its expertise in laboratory and analytical instruments/equipment?

Our product range includes advanced technologies like chromatography, mass spectrometry, spectroscopy, genomics, and diagnostics. These instruments are renowned for their precision, durability, and sensitivity, enabling customers to achieve breakthroughs in analytical excellence.

In addition to instruments, we offer comprehensive software, services, and consumables solutions to support the entire analytical workflow. We cater to customers in 110 countries across various industries, including pharmaceuticals, biopharmaceuticals, food, environmental, chemical, clinical diagnostics, research, and academia.

Could you share details about your company's revenues and expectations for the coming year?

Our company's revenues stand at $6.83 billion as of December 2023. While India continues to experience growth, we anticipate growth in all global markets as well. However, there are several uncertainties surrounding us, including rapidly changing macroeconomic conditions and conflicts in certain regions. Predicting growth projections requires considerable effort under such circumstances. Nevertheless, we are committed to surpassing market growth both in India and globally.

Are there any regulatory challenges hindering the growth of the industry as a whole?

From the biopharma standpoint, there are regulatory challenges for the biopharma sector.

Tough approval processes: Biopharma products undergo rigorous regulatory approval processes, which are often more complex and time-consuming than those of small molecules. This delays market entry and increases developmental costs.

Biological product complexity: Biotherapeutics are often very complex, making characterisation, standardisation, and consistency challenging as regulatory agencies require comprehensive data on product quality, safety, and efficacy.

Regulatory uncertainty: Changing regulations and evolving guidelines can create uncertainty for biopharma companies, impacting investment decisions and product development strategies.

Manufacturing and QC regulations: Biopharma products require stringent quality and manufacturing standards. Complex GMP and regulatory environments can be challenging for small or emerging companies.

Regulatory harmonisation: Regulatory requirements across different regions and countries can complicate global product development and commercialisation. Additionally, with new modalities emerging in the market, there are no harmonised guidelines developed yet, which adds to the complexity.

Could you share any outstanding new products or innovations your company has recently introduced to the laboratory sector?

Firstly, we have introduced Vaya Raman, a handheld and portable instrument based on Raman spectroscopy. This innovative device allows for quick raw material verification without the need to open containers or take samples to a lab for testing. Vaya Raman enhances productivity by swiftly qualifying raw materials, and its software is 21CFR compliant, making it suitable for regulated environments.

Another significant introduction is our Online LC solution, which bridges analytical and process worlds in process analytical technology (PAT) applications. This solution features an easy-to-access external sampling interface, enabling automated

process sample analysis via Liquid Chromatography (LC) applications.

Furthermore, we continue to advance Liquid Chromatography coupled with Mass Spectrometry (LC-MS) technology to support the growing biopharma industry. Our latest LC QQQ and LC QTOF platforms offer best-in-class 2DLC for enhanced separation power critical for complex biopharma analysis. Additionally, we provide automation solutions for precise sample preparation, minimising manual errors and enhancing confidence in analytical results.

We are also proud to introduce the Roteoanalyzer, a parallel capillary electrophoresis instrument designed for automated CE-SDS analysis of reduced and non-reduced protein samples. This system can separate 12 samples in as little as 30 minutes, streamlining the laborious process of SDS-PAGE gel preparation and analysis.

Lastly, we have revamped our Glycan analysis workflow with the introduction of Gly X and Amide HILIC columns. These fast-enabling sample prep kits and high-resolution columns facilitate faster and more accurate Glycan analysis of biotherapeutics, enhancing efficiency and precision in glycan analysis workflows.

What kind of support do you expect from the government to foster industry growth?

The government plays a pivotal role in fostering the growth of the biopharma sector. Currently, there is a strong focus on vaccine development, with substantial resources being allocated through agencies like BIRAC to support biopharmaceutical endeavours in India.

The government is actively promoting innovation and collaboration by sponsoring research and development (R&D) facilities, startups, and small and medium enterprises (SMEs) engaged in drug discovery, biomanufacturing, and analytical characterisation.

Furthermore, initiatives are in place to invest in skill development for individuals in the biopharma sector through partnerships with leading R&D institutes and private enterprises. These programmes aim to bridge the gap between academia and industry and promote a lab-to-market approach.

Public-private partnerships are instrumental in leveraging the strengths of academia to conduct crucial biopharmaceutical research, thereby driving innovation and growth in the sector.

In response to the post-COVID landscape, the government has made significant investments in infectious disease research, exploration of new therapeutic modalities, and support for emerging players, such as those involved in CART therapy development.

Are there any expansion plans or initiatives in place for setting up new centres of excellence or exploring new markets?

Yes, we've planned to establish a Center of Excellence (CoE) in Hyderabad's pharmaceutical and biopharmaceutical hub, which is currently attracting investments in the biopharma sector.

Furthermore, Agilent has entered into collaborations with CCAMP and IIT Delhi for application and skill development purposes. Additionally, we are in advanced discussions with potential collaborators to form partnerships in areas of mutual interest.

What future trends do you foresee in the laboratory and analytical instruments/equipment industry, both in terms of technology and market demand?

From a market perspective, new biopharma modalities such as peptides, oligo, mRNA, cell and gene therapy, ADCs, and bispecifics will drive the analytical markets. Increased focus on vaccines will continue to bring investments in various infectious diseases in the future. There will be much focus on having sustainable technologies or workflows that will improve productivity.

There will be a demand for analytical instruments that provide actionable insights from complex data for decision-making in R&D and production.

What is the current market size for laboratory and analytical instruments/equipment in India and globally?

The Indian analytical instrument market reached approximately $3.77 billion in 2023, highlighting its significance in the country's economy and scientific research. The market is expected to grow at a CAGR of 11 per cent by reaching approximately $9.65 billion by 2032. The analytical instrumentation market size is expected to grow from $ 49.47 billion in 2023 to $ 66.27 billion by 2028, at a CAGR of 6.02 per cent during the forecast period (2023-2028).

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