

INTERVIEW

Agilent continues to focus on strategic M&A, R&D investment to expand product portfolio

Samir Vyas, Country Manager, Agilent India says India companies are now moving into the global biopharma market and gives his views on the role of policies like Make in India/ *Atmanirbhar Bharat*, a more vigilant US FDA after the sartan episode and Agilent solutions for these challenges, in an interaction with **Viveka Roychowdhury**

India is termed the 'Pharmacy of the global South and is preparing to meet a sizeable portion of the global demand for COVID-19 vaccines. Where is the country ranked globally in the pharma and biopharma world?

There is no doubt that India has the potential, capability, and capacity to supply good quality and effective therapeutic, nutritional, and wellbeing products with higher affordability. India ranks third worldwide in the production of pharmaceuticals, where eight out of ten global generic companies are from this country. Although Indian companies are known for producing generic pharma drugs, many companies are now moving into the global biopharma market to enable revolutionised treatment and prevention of many disabling and life-threatening diseases. India is among the top 12 destinations for biotechnology in the world, with approximately three per cent share in the global biotechnology industry¹.

In recent times, India has strongly emerged as a global pharmacy, with the effective supply of critical medicines to over 150 countries. India is fast emerging as the vaccine



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hub for the world with the capacity of contributing around 60-70 per cent of the global vaccine supply for COVID-19.

But even with the many achievements, India finds itself critically dependent on external sources for crucial parts of the value chain like certain key starting materials and APIs, which need to be imported. How has this hampered the growth of the country's biopharma sector?

While it is true that India used to import almost 70 per cent of raw materials for pharma manufacturing, we focused more on building the capacity for finished products and continued our dependency on offshoring the starting materials². This pandemic has exposed and highlighted the need for India to come up with strategic initiatives and a robust plan to reduce the dependency of sourcing the starting materials and equipment for requirements as critical as public health care. Long manufacturing cycles and stringent quality standards resulted in low margins for pharma companies and encouraged them to import APIs, rather than produce

them domestically. Although, it has become evident that the impact of supply chain disruption was relatively less on the biopharma segment rather than the generic pharma industries.

Can policies like Make in India/Atmanirbhar Bharat set this balance, right? What is your take on this?

I am confident that these measures will facilitate growth for the Indian pharma/biopharma industries, thus creating a more self-reliant and sustainable ecosystem. We expect a more focused approach from the government with respect to capacity building, ease of doing business and growing investment towards infrastructure development. Having said that, it would be equally important to maintain excellent partnerships and continue collaborating with global companies to enable exchange of technology, competency, and experience in creating safe and affordable medicines.

Global regulators are becoming more stringent and holding pharma companies accountable for the quality of their

suppliers as well. The recalls of medicines with trace amounts of carcinogenic NDMA in medicines is a recent ongoing example. How can Agilent help companies for analysis and QC of input materials, as regulators up the ante by mandating more stringent testing at every point of the value chain?

The healthcare sector operates in a very dynamic environment and small changes in regulatory or safety guidelines have a significant impact. Historically, the pharmaceutical industry has been functioning with good manufacturing and laboratory practices and with time we have seen the journey of regularity and compliance evolution to provide the safest medicine. During FY 2015-19, we saw a rising trend with an increase of 'warning letters' issued by the US Food & Drug Administrator (FDA), whereas FY 2020 has shown a significant drop which is likely due to restriction in travel/inspection because of COVID-19.

Another major focus area for regulators is to evaluate and reshape the carcinogens risk assessment in human drugs. After the Sartan episode, the FDA is becoming more and more vigilant and asking manufacturers to identify the root cause of these nitrosamine impurities and to prevent the recurrence of this episode in the future. At Agilent, we have established the cutting-edge Geno Toxic Impurity (GTI) analytical workflow, which includes a combination of advanced technology, high-throughput sample preparation, and an integrated and compliant software platform. To provide trusted answers to our customers, we need to work with them at each step of their value chain. It is essential that we address challenges at the R&D stage, all the way until the finished product is released. Our solution readiness with a strong service network has really helped in setting up a robust and reliable

analytical methodology at our customers' laboratories.

Regulators are also demanding more documentation to record test results from QC and R&D labs as well as the manufacturing plants. What are some of the technology solutions that pharma companies will need to deploy to stay on top of evolving regulations? The common myth is that the applicable regulations are new. But 21 CFR Part 11, Electronic Records; Electronic Signature was first released in 1997³. As the regulatory norms have become more and more

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stringent, the evolution from lab informatics is becoming a silver lining. Credible lab results depend on the quality and reliability of testing data, regardless of which industry or function the lab serves. An end-to-end integrated, and harmonised software platform plays a key role in enabling effective lab compliance. Agilent is constantly investing to expand its lab informatic portfolio and with the successful acquisition of Genohm, we have got the new capability of LIMS, workflow management, and expansion of ELN capability to help lab users in generating more reliable and efficient results. Now the Agilent's OpenLab Software portfolio is an integrated suite of products that includes sample management, data acquisition, data analysis, data management, and lab workflow management.

With increased documentation, data

integrity issues and possibilities of manual errors increase. What are the automation solutions available?

Agilent recognises the pain point of our customers around the manual approach in managing both high and low throughput areas of their laboratory. Most laboratory challenges are associated with data handling and sample preparation. To enable automated data handling, Agilent provides an end-to-end integrated software solution, which covers the analytical workflow from the moment the analytical request is generated until the data are archived. We have also built

automation capability into the sample preparation side, as manual sample preparation can be variable and error-prone leading to time-consuming rework and poor results. Agilent's patented AssayMAP Bravo sample prep platform provides complete automation and ensures consistent, reproducible, and faster results. While automation is becoming an integral part of each advanced laboratory, we also ensure that it comes with ease of operation as well as affordability.

What are the new technologies and solutions in the pipeline?

While Agilent continues to focus on strategic M&A, we are also committed to R&D investment for expanding our compelling product portfolio for addressing emerging complex analytical testing challenges. We see changes to the landscape of an analytical laboratory, where there is a higher

demand for reducing the cost and increasing turnaround times without compromising on the reliability of the results. It becomes very important for a technology partner like Agilent to work very closely with its customers and understand their unmet needs so our innovations can make the right contribution to the laboratory's success.

One of the focus areas for Agilent is to expand its capabilities and offer a complete biopharma workflow solutions portfolio. Our biopharma customers are moving away from classical offline QA/QC to more online/at-line testing,

so they can decrease associated manufacturing costs and have a faster and more efficient release of the final product. Our biopharma strategies are very much focused on developing several analytical techniques so that we can provide trusted answers to the emerging and challenging needs of the current laboratory. The successful acquisition of Cobalt, ProZyme, and BioTek add core value to our existing biopharma portfolio, which already comprises cutting-edge technologies like 1290 Infinity II Bio LC, 6545XT Bio Q-TOF, and AdvanceBio analytical columns.

Along with a focus on product innovation, we continue building our strong service network and expanding new compliance services to ensure our customers get a one-stop solution with peace of mind when they choose Agilent. In addition to our industry-leading qualification services

portfolio, we have now added a computer system validation and lab management solution, called iLab.

What has been the investment of Agilent in India, in terms of headcount, facilities etc.? Any expansion plans for the India market?

India is one of the geographies for Agilent where we see great potential and we will continue to focus on expanding our local footprint. We have an industry-leading talented team of more than 500 employees in India that work with our customers which represent almost every leading sector. We have about 10 sales offices across India and three Center of Excellence laboratories to ensure we stay in good proximity with our customers from the North, South, and West parts of the country. Agilent has made a significant investment in the Manesar campus, where there are about 1100 plus employees focusing on global support services.

Agilent is also committed to academia-industry collaboration; bringing new initiatives to support research and skill development. This year Agilent's global Thought Leader Award was conferred to IIT-Delhi Professor Anurag Rathore for his contributions in the field of biopharma research. We are looking forward to driving more academia-based collaborations, which can help improve quality of life.

References

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