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Why Automate Bioreactors?

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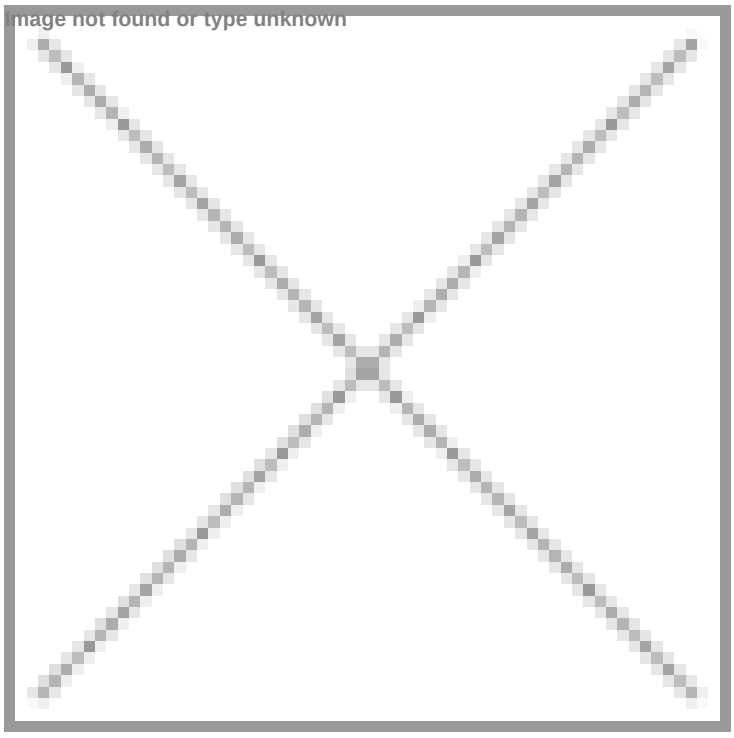
Automation and controlled monitoring have made in-roads to modernise several industries. Bioreactors too became more automated and heavily monitored using diagnostic sensors, leading to improved efficiency and consistency offering better product yields and higher speed-to-market. Technologies like Artificial Intelligence (AI) and Machine Learning (ML) are deployed in bioreactors to make bioprocessing systems score higher in their performance thereby increasing production of biopharma products at a faster rate. As India's biopharma market is booming, let's look into the market scenario for automated bioreactors in the country.



Bioreactors are used extensively in biopharmaceutical space to produce biological drugs (such as, proteins/peptides, antibodies, or vaccines). Automation, thus, offers vast potential in optimal design, monitoring, and control of biopharmaceutical manufacturing. Advanced software integrated into bioreactors enables real-time monitoring, data analysis, and process control. This allows for precise adjustment of parameters such as temperature, pH, agitation, and nutrient supply, optimising bioproduction processes for higher yields, quality, and efficiency.

Several market research reports indicate that the driving forces for adoption of AI/ML techniques include the growing global demand for biotherapeutics and the shift towards Industry 4.0 spurring the rise of integrated process platforms and continuous processes that require intelligent, automated supervision.

"Automation stands as the beacon of efficiency and consistency in bioreactor operation," says **Arun Luthra, Founder and CEO of Amerging Technologies**, one of India's leading bioprocess equipment manufacturers. He says, "Unlike manual processes, which are prone to human error and variability, automation ensures precision and reproducibility at every stage. This reliability translates into enhanced productivity, reduced downtime, and ultimately, cost savings. Moreover, automation

facilitates seamless data collection and analysis, empowering researchers with real-time insights into process parameters." According to Luthra, by harnessing automation capabilities, bioreactor operators can optimise conditions, troubleshoot issues promptly, and accelerate the pace of scientific discovery.

Bringing forth another critical perspective to the advantage of automating bioreactors, **Kumarasamy K, Chief Technical Officer, BPE Biotree**, says, "Automation ensures that processes are performed consistently and reproducibly, reducing variability between batches by referring the previously executed golden batches. This consistency is critical in industries such as biologics, pharmaceuticals, where product quality and regulatory compliance are extremely important."

Elaborating further, Kumarasamy, says, "Automated bioreactor systems can collect and record vast amounts of data in real-time and archives the same for future analysis, providing insights into the fermentation process that would be difficult or impossible to obtain manually. This data can be analysed to optimise process parameters, identify trends, alarms, version control/audit trail and troubleshoot issues more effectively. The collected data will, hence, be readily available for auditors as and when required."

Speed to market

One of the significant reasons for a sudden spruce in bioreactor manufacturing was COVID-19. The high demand from governmental vaccination programmes and private entities to vaccinate large sections of the population required scientists to work under pressure to shorten the time-to-market of developed vaccines. And, procuring automated bioreactors offered significant advantages in accelerating the speed at which vaccines and other bioproducts reached the market.

Advanced automated bioreactors can facilitate continuous manufacturing, where production runs uninterrupted. This eliminates downtime between batches and significantly reduces overall production time.

Thermo Scientific, for example, has deployed high-performance software control platforms, that enhances both user experience and data aggregation. A software-led distributed control platform facilitates easy integration of multiple bioreactors to streamline process control and data management from research to production. Thermo believes that this software interface helps to minimise the engineering effort and time spent when navigating through the process stages of production, especially vaccines, and biomanufacturing, when speed to market is very critical.

Similarly, Sartorius asserts that by incorporating software functionalities, its bioreactors have become more intelligent, accelerating R&D timelines for biopharmaceutical products. Sartorius' bioreactors are specifically designed and pre-engineered with software components from the ground up. The company has developed a configuration toolkit, which has a library of templates that provide standardised configuration. Using the library, the production teams can integrate several bioreactors into their control system quickly. This increased automation reduces the need for manual operation, which ultimately increases quality and speeding up time-to-market.

From the user point of view, Pfizer, one of the world's premier biopharmaceutical companies, uses ML and AI for near-real-time monitoring of its mammalian cell culture bioreactors to boost batch yield and reduce the risk of contamination. Using Amazon Web Services (AWS), the company developed Manufacturing Intelligence Edge (MI Edge), a platform that uses AI and ML for continuous monitoring of bioreactors at its global manufacturing sites. MI Edge increased the frequency of measurements from one sample per day to near-real-time monitoring every few seconds. This improved frequency, according to Pfizer, helps operators to adjust parameters as needed throughout the batch, resulting in greater yield, delivering more medicine for patients, faster.

Steady progresses

The bioreactor market in India is expected to reach $164.8 million in 2027 from $94.6 million in 2018. The market is estimated to grow with a CAGR of 6.6 per cent from 2019-2027, according to Insight Partners' report. The growth of the bioreactors market is primarily attributed to the increasing number of bioreactors manufacturers, speedy evolution of pharmaceutical industry and aggressive pharmaceutical and biotechnological activities. Additionally, the growth is also contributed to factors such as opportunities to develop personalised medicine.

There are over 100 companies who are into manufacturing of bioreactors in the country, according to tradeindia.com. Some of the leading names in this space include Fermex Solutions, Shree Biocare Solutions, Uma Pharma, BPE Biotree, Prime Care Technology, Krishna Scientific Suppliers, Amerging Technologies, OmniBRx Biotechnologies, SM Biosystems, IMEMFLO, Biozeen, Bangalore Biotech Labs, Praj Hipurity Systems, Labindia Instruments, Thermo Fisher Scientific India,

Merck Millipore India, Globe Scientific Inc, Solaris Biotechnology, Infors HT (Labmate (Asia), Eppendorf India, Sartorius Stedim Biotech India, Applikon Biotechnology, and GE Healthcare.

In the past few years, India has been witnessing significant investments in the development of modern bioreactors. In March 2023, bioprocess engineering company, OmniBRx Biotechnologies secured $5 million Series-A funding from SIDBI Ventures and others. OmniBRx used the funds to expand into overseas markets and strengthen its product portfolio of single-use bioreactors. The company noted that scalable and efficient bioprocessing technologies, specifically the single-use bioreactor platforms are in high demand worldwide for the production of vaccines and other biologicals.

Several reasons can be attributed to the demand for bioreactors. India's biopharmaceutical sector has been expanding rapidly due to increasing investments in R&D, rising demand for biologics, and a favourable regulatory environment. Bioreactors play a crucial role in the production of biopharmaceuticals such as vaccines, monoclonal antibodies, and recombinant proteins. The competitive landscape in India's biopharmaceutical industry is also pushing companies towards adopting automated bioreactors. And Indian biopharmaceutical companies are increasingly competing with established players globally.

“Automation also plays a critical role in meeting regulatory requirements for approval, ensuring consistency and reliability in production processes. It's crucial for providers to customise their offerings to meet the diverse needs of buyers, ensuring market expansion and long-term success,” opines Arun Luthra.

It’s safe to conclude that in India, the convergence of IT and BT is spurring a huge demand in developing automated bioprocess equipment. Hiring of candidates, in India, with specialisation in process and mechanical design and fabrication of bioreactor equipment coupled with knowledge in software technologies will be trending for long.

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