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Advancing India's Next Generation of Biopharma Manufacturing

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Indiaâ??s pharmaceutical and biopharmaceutical manufacturing landscape is entering a new phase, driven by the convergence of digital technologies, artificial intelligence (AI) and advanced process analytics. As global regulators place greater emphasis on process understanding, data integrity and consistent product quality, digital bioprocessing is becoming increasingly important for Indian manufacturers. The integration of Process Analytical Technologies (PAT), AI-driven analytics, automation and Real-Time Release Testing (RTRT) can help improve efficiency, reduce batch variability and accelerate product release. For Indiaâ??s growing generics, biosimilars and vaccine ecosystem, this digital transformation could strengthen competitiveness and support the countryâ??s ambition to become a global biomanufacturing hub.

The pharmaceutical and biopharmaceutical manufacturing sector in India is evolving into a more data-driven and intelligent ecosystem, as global regulatory bodies continue to emphasise better process understanding, batch consistency, and supply chain resilience. Digital bioprocessing systems, AI-enabled PATs, and RTRTs now allow for the continuous control of the manufacturing processes and quicker product release. For India’s robust base of production of generics, biosimilars, and vaccines, this technology is going to improve efficiency of operations, increase competitiveness, and help with implementation of high-value biomanufacturing initiatives, such as the PLI scheme.

The Shift to Digital Bioprocessing

Digital bioprocessing refers to the integration of sensors, automation, historian systems, manufacturing execution systems (MES), and analytics platforms across upstream and downstream operations. In classical biopharmaceutical practices, data from bioreactors, chromatography and filtration units are accumulated in isolated silos, their behavior is analysed manually, and data are reconciled at the end of the batch. However, a modern plant is constantly streaming data from single-use and stainless-steel bioreactors, at-line and in-line analysers into a centralised database or historian data storage, thus enabling comparisons with data on batch genealogy, raw material lots and equipment maintenance history. Consequently, this approach allows for advanced analytics since the absence of reliable, time-synchronised and contextualised data significantly limits AI implementation. In India, it is typical to start this process with digitising batch records, then connecting elementary equipment to a data backbone and finally integrating with advanced analytical software.

Why Digital Bioprocessing Matters for India

Conventional fermentation and cell-culture batches in India are still mainly supervised through offline sampling processes, laboratory tests and extensive paperwork. Cycle times are long, differences between batches are significant, and yield losses of 10 to 20 per cent remain common in many conventional manufacturing environments. With biosimilars, mRNA vaccines, cell therapy and gene therapy, as well as precision fermentation showing up in India's pipeline, these manual methods are no longer sustainable. Regulators such as Central Drugs Standard Control Organisation (CDSCO), US Food and Drug Administration (FDA) and European Medicines Agency (EMA) demand more data integrity, constant process verification and Quality-by-Design (QbD) proofs that only digital systems can provide in sufficient manner.

The Three Building Blocks

- **PAT:** Using devices like Raman, NIR, dielectric spectroscopy, capacitance, dissolved-oxygen, and off-gas analysers, systems for in-line and on-line measurements can identify critical quality attributes (CQAs) such as titer, glycan profiles, and purity.
- **AI & Machine Learning:** Using soft sensors and hybrid mechanistic and machine-learning models, organisations can transform PAT output signals into forecasts of yield, impurity levels, and batch quality, often hours before conventional measurements are available.
- **Real-time Control & Digital Twins:** Using model-predictive models and simulate bioreactor, chromatography, and fill-finish operations using real-time process data, enabling predictive control over pH, temperature, or feed rate.

The Indian Landscape

The adoption of PAT technology is progressing unevenly but gaining momentum. Significant players such as Biocon, Serum Institute of India, Bharat Biotech, Dr. Reddy's, Zydus Lifesciences and Panacea Biotec have integrated bioreactors using PAT technology and MES/DCS framework in their operations. Contract development and manufacturing companies such as Syngene, Aragen, Enzene, and Biological E, have established AI-supported process development labs to lure global innovators. Various public initiatives, including the National Biopharma Mission (NBM) and Biotechnology Industry Research Assistance Council (BIRAC), are helping foster open PAT datasets, digital-twin reference benchmarks, and workforce development in bioprocess informatics.

Under the BioE3 Policy in place, India has committed itself to creating a nationwide cluster of biotech factories, biomanufacturing plants, and Bio-AI centres with the aim of speeding up the introduction of bio-based products into vital industries. Apart from these objectives, the policy puts an accent on the need for collaborations between the public and private sectors, as well as skill development and infrastructure sharing, making India’s biomanufacturing ecosystem more sustainable.

Measurable Impact

Early industry experience from monoclonal antibody and vaccine manufacturing programmes in India suggests that AI-driven PAT and RTRT can reduce development times by up to 40 per cent and increase titers by up to 25 per cent.This approach, which involves in-line sensors and closed-loop automation, further reduces batch deviations by 30–50 per cent and lowers COGS by 15–30 per cent. RTRT, which is still in its infancy in India, can reduce quality assurance time for manufacturing from weeks to hours. This is particularly useful for the manufacture of living and perishable medicines during a pandemic.

Challenges Unique to India

- Updating dated brownfield plant infrastructure with sensors and data systems is still expensive and intrusive to operations.
- The lack of integrated data systems has left many plants relying on hard copy records or isolated Supervisory Control and Data Acquisition (SCADA) systems which hamper digital conversion.
- Another barrier to adoption is the lack of skilled professionals with knowledge of bioprocessing, automation and AI/ML.
- Regulatory agencies are pushing for a systemised education of employees in AI model development and regulation, compliant AI and validation methods.
- The need for increasing data security and sovereignty is growing as OT and IT are merging in GMP settings.

The Road Ahead

India is expected to adopt a PAT-first manufacturing approach, with new facilities in Hyderabad, Bengaluru, Pune, and Gujarat’s bulk drug parks likely to be designed from inception as sensor-driven and cloud-ready. CDSCO is expected to develop further regulatory guidance for PAT, RTRT, and AI/ML under GMP, aligned with ICH Q8–Q14 and evolving FDA AI frameworks. The country is also expected to develop sovereign AI models for bioprocessing, leveraging Indian datasets, media formulations, and climatic conditions, with domestic cloud hosting anticipated to support intellectual property protection and compliance with the Digital Personal Data Protection Act (DPDPA).

Conclusion

For global biomanufacturing, digital bioprocessing is emerging as a requirement instead of a differentiating factor. In the context of India, the combination of AI, PAT, and real-time control gives a unique opportunity for the country to transform itself from using batch and paper methods for production to becoming a self-operating factory. If successfully implemented at scale, these technologies can strengthen India's position not only as the pharmacy of the world, but also as a globally recognised

hub for intelligent, digitally enabled biomanufacturing.

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