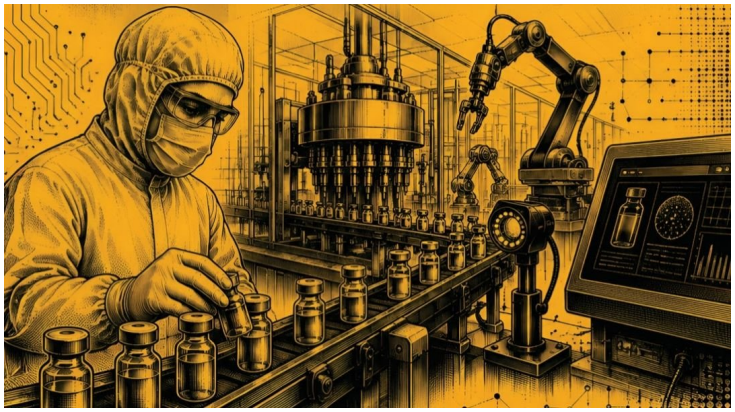
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Digital Bioprocessing Tools Powering Indian Pharma

01 September 2026 | Features | By Ayesha Siddiqui

Much like digital technologies have become an indispensable part of everyday life, they are now transforming one of the world's most tightly regulated industries: pharmaceuticals. For decades, Indian drug manufacturers built their global reputation on cost-efficient production and large-scale manufacturing. Today, however, competitiveness is increasingly being defined by digital capabilities. From Manufacturing Execution Systems (MES) and electronic batch records to Laboratory Information Management Systems (LIMS), artificial intelligence (AI), predictive maintenance and smart factory technologies, pharmaceutical companies are digitising manufacturing operations to improve quality, strengthen regulatory compliance, reduce production costs and accelerate time to market. According to Archimedis Digital's State of Digital Transformation in Indian Pharma 2025 (Quality Edition), more than 88 per cent of Indian pharmaceutical companies have initiated digital transformation in quality functions, with one-third already achieving significant or enterprise-level maturity. As India's pharmaceutical industry moves beyond traditional manufacturing towards Pharma 4.0, we explore the digital bioprocessing technologies driving this transformation, the companies leading the shift, and the tools that are becoming essential for building the next generation of smart biomanufacturing facilities.



Unlike many other manufacturing industries, pharmaceutical production demands absolute precision, data integrity and regulatory compliance. Every stage, from raw material testing and upstream processing to formulation, packaging and batch release, generates vast amounts of data that must be captured, analysed and maintained in accordance with global regulatory requirements. The growing development of complex therapies, including biologics, cell and gene therapies, and other advanced modalities, has further increased manufacturing complexity, making robust digital systems essential for ensuring process consistency, product quality and regulatory compliance.

"As bioprocessing becomes increasingly complex, the ability to transform data into actionable insights is becoming a key differentiator. Advances in automation, AI and digital technologies are helping manufacturers optimise workflows, improve process consistency and make faster, more informed decisions. As a trusted partner to our customers, we're focused on combining innovative technologies with scientific expertise to help them increase productivity, advance scientific breakthroughs and bring new therapies to patients faster," said a spokesperson from Thermo Fisher Scientific.

Beyond improving operational efficiency, digital technologies are also becoming indispensable for meeting increasingly stringent regulatory expectations.

"Indian pharma's digital shift is now being driven more by necessity than ambition. Data integrity issues have been a major reason for FDA warning letters to Indian manufacturing sites in recent years, making electronic, auditable and connected systems a baseline requirement rather than a competitive advantage. From MES and digital twins to serialisation platforms, these technologies are helping companies strengthen compliance while improving operational efficiency," said **Hari Kiran Chereddi, Founder, MD and CEO, HRV Pharma.**

The Tools Powering Pharma 4.0

Indian pharmaceutical manufacturing is being rebuilt, plant by plant, around a small set of software categories such as MES, Quality Management Systems (QMS), LIMS, digital twins, Process Analytical Technology (PAT), serialisation and supply chain platforms, and AI. This marks a significant shift from the digitalisation efforts of five years ago, when technology adoption was largely confined to basic functions and standalone systems.

Manufacturing Execution Systems (MES): It handles batch execution, electronic batch records, and shop floor traceability. It is the most invested-in category in Indian pharma manufacturing today.

“An Indian CDMO using PAS-X or OpCenter across multiple lines can shift from paper-based batch review to ‘review by exception,’ where only flagged deviations need manual QA approval. This change often reduces batch release cycle times from days to hours,” said Chereddi.

Some common system names that keep coming up for consideration are as follows.

- Körber Pharma's PAS-X (formerly Werum) is the closest thing to an industry standard; it is particularly strong in biologics, sterile manufacturing, and cell and gene therapy environments. It is widely used across large-scale CDMO operations. It has been adopted by leading Indian pharmaceutical companies, including Lupin, Cipla and Dr. Reddy's.
- Siemens OpCenter Execution Pharma combines MES with Siemens' broader digital twin and automation tools, allowing manufacturers a single digital thread from recipe design to production analytics.

- Rockwell Automation's Pharma Suite, now utilising a containerised, Kubernetes-based cloud architecture, is being adopted for multi-site rollouts, where flexible scaling across plants is important.
- Cloud-native platforms like Tulip are attracting mid-sized manufacturers who need quicker validation cycles without a lengthy, on-premises setup.

“Tulip is a no-code, cloud-native MES built specifically to avoid the cost and change-control burden of traditional systems. Mid-size manufacturers use it to digitise batch records and SOPs in days rather than months, without hiring integrators,” said **Saurabh Agarwal, Director at HAB Pharma.**

Quality Management Systems (QMS): A unified QMS allows Indian pharmaceutical exporters to manage deviation and CAPA records through a single system that supports audit requirements across the FDA, EMA and multiple emerging market regulators, reducing duplicate documentation and improving compliance efficiency.

Some commonly used ones are:

- Veeva Vault QMS seems to be the most widely used cloud QMS in life sciences. It covers CAPA, deviations, change control, and supplier quality in one system. The vendor manages regular updates to regulatory content, easing the load on internal IT teams. Several global companies such as AstraZenca, Sanofi and Indian companies such as Kemwell BioPharma, Bharat Serums and Vaccines are customers.
- MasterControl seems to have a strong market presence in mid-sized pharma and biotech; it is often chosen for combining QMS and MES-lite features.
- Sparta Systems' TrackWise and ETQ Reliance are still common in Indian plants that adopted QMS earlier and haven't yet moved to cloud-native systems. Biocon and Navitas Life Sciences are the customers.

Besides these “Qualio is the go-to affordable QMS for small and mid-size life sciences companies — document control, training, CAPA, and audit readiness, with pricing built for smaller teams and fast onboarding rather than a multi-year enterprise rollout. And QT9 QMS is another cloud-based, quick-deploy option mid-size manufacturers use for CAPA and audit management at a fraction of enterprise QMS cost,” said Agarwal.

Laboratory Information Management Systems (LIMS) and electronic lab notebooks: Experts note that the greatest benefits of LIMS are realised when it is integrated with MES. Such integration enables seamless data flow between laboratory and production systems, reducing manual data entry, improving data integrity and accelerating batch release.

Among the commonly used LIMS and electronic laboratory notebook platforms are:

- LabWare LIMS and Thermo Fisher's SampleManager are seen as the main platforms in most Indian QC laboratories; they manage sample tracking, testing, and Certificate of Analysis generation.
- Benchling has made strides specifically in biologics-focused R&D and process development labs for electronic lab notebook and registry functions. The company claims that nearly 500 biotech companies from AI-native startups to top-20 pharma, are using it.

Digital twins: They allow biologics manufacturers to simulate changes in critical process parameters, such as temperature, agitation and nutrient feed, before implementing them in a real bioreactor. This enables manufacturers to evaluate their impact on cell growth and product yield in a virtual environment, significantly reducing the risks associated with scaling complex biologics.

Commonly adopted digital twin solutions include:

- Siemens' Xcelerator/OpCenter combination looks to be the most commercially used digital twin technology in pharma manufacturing today. It simulates bioreactor and fermentation conditions and predicts critical process parameter shifts before they impact a batch.
- Dassault Systèmes' BIOVIA and 3DEXPERIENCE platforms are more focused on process development and technology transfer, modelling how a process will act before scaling to commercial volume.
- NVIDIA Omniverse is worth watching. It is genuinely used in pharma, but adoption is still mainly among larger multinational biologics manufacturers performing facility-level simulations, rather than Indian mid-market CDMOs, who are one to two cycles behind in this category.

Supply chain and serialisation: For Indian API and formulation exporters, serialisation platforms are now an essential component of digital manufacturing. By enabling end-to-end product traceability and compliance with country-specific regulations, they help ensure that shipments clear customs efficiently and reach their intended markets without disruption.

- TraceLink and SAP Advanced Track and Trace are the leading solutions for serialisation compliance, essential for any Indian exporter shipping to the US (DSCSA) or EU (FMD) markets. TraceLink has 1,000 customers in 43 countries.
- Kinaxis Maestro and o9 Solutions are frequently mentioned for demand and supply planning at larger Indian manufacturers handling multiple destination markets at the same time.

“Smaller regional serialisation vendors (over TraceLink's global network) are increasingly used by exporters focused mainly on a few key markets, where the cost of a full global network isn't justified,” said Agarwal.

Process Analytical Technology (PAT): Several leading Indian generics manufacturers have invested in continuous manufacturing to support faster US ANDA approvals, with PAT serving as the sensing and real-time monitoring backbone of these production systems.

Raman and near-infrared spectroscopy instruments from vendors like Mettler Toledo and Bruker are becoming standard on Indian continuous-manufacturing lines, providing real-time process data to MES and digital twin models.

Artificial Intelligence (AI): Of course, no discussion on digital transformation is complete without AI. While AI has already become an integral part of drug discovery and research and development (R&D), its role in manufacturing is now expanding rapidly. Broadly, AI is being adopted in two ways. The first is through general-purpose AI platforms such as ChatGPT and Claude. The second is through AI capabilities embedded within existing manufacturing and quality systems.

“Rather than a separate AI product, generative AI is being built directly into the ERP and QMS layer. The clearest example: SAP has embedded Anthropic's Claude as the reasoning engine inside Joule, its AI assistant across S/4HANA, procurement, finance, and supply chain. A planner can now ask a plain-language question about a batch or a supplier delay and get an answer — or have the system act on it directly — instead of navigating multiple screens. SAP has also opened its AI Foundation hub to other models, including OpenAI's GPT and Google's Gemini, so companies aren't locked into one AI vendor.” said Agarwal.

Separately, and more informally, teams are using ChatGPT and Claude directly — drafting SOPs and deviation reports, summarising batch investigation data, generating first-pass regulatory correspondence, and querying large documents like validation protocols.

“These aren't validated GxP systems, so most companies restrict their use to drafting and review support rather than anything that touches the batch record itself. That's a sensible line for now — AI drafting a deviation summary for a human to check is very different from AI approving a batch. For mid-size pharma companies specifically, this is the most cost-effective entry point into AI: no new platform to buy, no lengthy validation project — just smarter use of tools already licensed, with clear guardrails on what stays human-approved,” said Agarwal.

How India's Pharma Leaders Are Digitising Manufacturing

Here's how some of India's leading pharmaceutical companies are embracing digital manufacturing.

Lupin

'At Lupin, every digital investment traces back to one question: does this get high-quality medicine to our patients faster, more reliably, and more sustainably? That question shapes how we have built our Global Technical Operations function over the past two years — bringing manufacturing, quality, supply chain, procurement, and sustainability under one integrated operating model, rather than treating digitalisation as a series of standalone tools. That integration shows up most concretely on the shop floor” said ***Christoph Funke, Chief Technical Operations Officer, Lupin.**

Across its manufacturing network, the company has scaled Manufacturing Execution Systems (MES), PAS-X electronic batch record solutions, Laboratory Information Management Systems (LIMS), Industrial IoT platforms, and real-time analytics to strengthen traceability, data integrity, and right-first-time execution. For example, at its Tarapur and Nagpur facilities, centralised data acquisition and Industrial Internet of Things (IIoT) integration provide real-time batch monitoring and batch-to-batch analytics, while electronic batch records have significantly reduced manual documentation and shortened review-and-release timelines. In quality control, Quality Prism connects LIMS, analytical instruments, SAP, and smart laboratory technologies into a single digitally linked ecosystem, enabling quality decisions to be made using live data rather than delayed information.

The company is also advancing predictive manufacturing through Quality Pulse, which provides enterprise-wide quality monitoring, and RADAR for predictive quality analytics. In addition, MMIH (Manufacturing and Maintenance Insights Hub), its Generative AI initiative, is designed to anticipate process risks before they become deviations, shifting quality management from reactive to proactive.

“None of this is technology for its own sake. It's how we operationalise the six pillars our GTO strategy is built on — regulatory compliance, customer focus, technology, and cost leadership, ESG and capability building— at the scale of a 12,000-person global operations network. The platforms give us the traceability and foresight; the people running them are what turns that into consistent, dependable delivery for our patients,” said Funke.

Dr. Reddy’s

Dr. Reddy's is leading the charge in digital bioprocessing, with its Bachupally manufacturing facility recognised by the World Economic Forum as a Global Lighthouse Factory for its adoption of Industry 4.0 technologies. The company has implemented a suite of digital manufacturing tools, including Körber's Werum PAS-X Manufacturing Execution System (MES), AVEVA PI System for real-time industrial data management, digital twins, Industrial Internet of Things (IIoT), advanced analytics, robotic process automation (RPA), digital performance management, and augmented, virtual and mixed reality (AR/VR/MR) as part of its "OpsNext" transformation programme. Together, these technologies have enabled real-time monitoring, predictive insights and process optimisation, contributing to a 43 per cent improvement in manufacturing costs, a 30 per cent reduction in production lead time and a 41 per cent reduction in energy consumption.

Biocon

Biocon is advancing its digital manufacturing journey across its biologics business through a range of Industry 4.0 initiatives aimed at improving operational efficiency, quality and regulatory compliance. The company has implemented electronic batch manufacturing records (eBMR), Laboratory Information Management Systems (LIMS), Electronic Document Management Systems (EDMS), Learning Management Systems (LMS), SAP Plant Maintenance (SAP-PM), Asset Management Systems (AMS) and the TrackWise electronic Quality Management System (eQMS) across its manufacturing operations. Biocon has also digitised equipment qualification and process validation activities, introduced paperless laboratory workflows and piloted an AI/ML-powered natural language processing (NLP) tool to accelerate investigation report reviews, reducing cycle times and enhancing responsiveness.

Cipla

Cipla is accelerating its Pharma 4.0 journey through the deployment of advanced digital manufacturing technologies across its production network. At its Patalganga facility, the company implemented Körber's Werum PAS-X Manufacturing Execution System (MES) and Electronic Batch Records (EBR), digitising operations from dispensing to dispatch through full integration with production, manufacturing and enterprise systems. The rollout has since expanded to its Indore and Goa facilities. According to Körber, the implementation reduced manual data entry by approximately 75 per cent, streamlining production documentation, GMP logbooks and batch review processes while improving data integrity and operational efficiency. Cipla has also adopted Siemens PCS 7 as part of its continuous manufacturing facility at Kurkumbh, enabling automated process control, real-time monitoring and greater manufacturing flexibility as the company advances towards touchless factory operations.

Zydus

Zydus Lifesciences is taking digital manufacturing a step further with its new Ahmedabad SEZ Unit III oral solid dosage facility, designed as a highly automated "lights-out" factory with minimal human intervention. The facility combines AI-enabled analytics, robotics, Automated Guided Vehicles (AGVs), Autonomous Mobile Robots (AMRs) and Process Analytical Technology (PAT) to enable predictive, data-driven manufacturing and real-time process control. Across its manufacturing network, the company has also strengthened its digital ecosystem through Laboratory Information Management Systems (LIMS), electronic data management systems, Tableau-powered real-time analytics dashboards, paperless Computer System Validation (CSV), digital Annual Product Quality Review (APQR) and process validation platforms, Robotic Process Automation (RPA), IoT-enabled energy monitoring, and the Factorian machine integration dashboard.

What makes India's digital transformation journey distinct?

While pharmaceutical manufacturers worldwide are embracing digital technologies, experts believe India's transition has several defining characteristics that set it apart from trends in the US and Europe.

“First, this change is publicly led by specific CIOs and CDOs at major Indian companies, not just highlighted in vendor case studies. This adds credibility to the story instead of relying on broad industry commentary,” said Chereddi. The regulatory environment has also emerged as a major catalyst for digital adoption.

“Second, the primary driver for adoption is both defensive and transformative: data integrity and 21 CFR Part 11 compliance pressure has accelerated adoption in India more than the "innovation" narrative alone would indicate,” said Chereddi.

India's expanding CDMO and outsourced manufacturing sector is also influencing technology adoption, as companies increasingly require digital platforms that can support multiple customer audits and compliance requirements through a single system.

“Third, India's shift towards CDMO and outsourced manufacturing alters the meaning of "widely used." With most of India's pharma manufacturing capacity now serving multiple customers instead of a single owned brand, the platforms gaining the most rapid adoption are the ones that allow a single MES or QMS instance to meet several customers' audit requirements simultaneously. This is a unique dynamic that is reshaping vendor selection in the industry,” said Chereddi.

Experts also point out that while big companies continue to invest in comprehensive enterprise systems, many mid-sized manufacturers are pursuing a different path, prioritising solutions that can be deployed more quickly and at a lower cost.

“Large multinationals run the expensive, deeply validated suites — Werum PAS-X, Rockwell PharmaSuite, Veeva Vault. But most of India's mid-size pharma companies, and a growing number of mid-size players globally, are choosing differently. They're going for cloud-native, faster-to-deploy, lower-cost tools that don't need a two-year validation project or a dedicated IT army to run. That's really the more interesting story right now — how the mid-market is closing the digital gap without the enterprise price tag,” said Agarwal.

Although digital transformation is gaining momentum, the journey is still in its early stages. According to the Archimedis State of Digital Transformation in Indian Pharma 2025 report, only 33.3 per cent of organisations have achieved significant or enterprise-level digital maturity, with fully integrated systems replacing fragmented legacy approaches. As more pharmaceutical companies invest in these tools, the industry is expected to move towards increasingly connected, data-driven manufacturing.

Ayesha Siddiqui