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Building Digital Foundation for Biomanufacturing

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Biopharmaceutical manufacturing is moving beyond conventional process monitoring towards connected, predictive and increasingly autonomous operations. The convergence of Process Analytical Technology, real-time data, AI, digital twins and advanced process control is enabling deeper process understanding, earlier intervention and more consistent product quality. For biopharma companies and CDMOs, building an interoperable digital foundation will be critical to scaling next-generation manufacturing.

Biopharmaceutical manufacturing is entering a period of significant change. With over 2000 biological therapeutics in development covering modalities such as cell and gene therapy, antibody drug conjugates, monoclonal and bispecific antibodies, the existing bioprocessing capabilities do not meet the rising demands of the complex next generation therapeutics. Conventional approaches built around fixed process settings, periodic sampling and end-of-process testing are increasingly being complemented by technologies capable of providing much greater visibility into a bioprocess while it is running.

The integration of Process Analytical Technology (PAT), connected process data, advanced analytics, artificial intelligence (AI), digital twins and process-control technologies across bioprocess development and manufacturing is transforming bioprocessing. Advanced PAT is enabling real-time release testing to predict and track product quality for product quality assessment. The ability to monitor bioprocessing data in real-time is critical for continuous biomanufacturing for the growing

production of next-generation therapies.

Ongoing developments in digital bioprocessing opens a significant opportunity for biopharmaceutical developers to move from reactive process control to predictive process intelligence.

Moving from offline testing to real-time process understanding

Traditionally, biopharmaceutical quality assurance and control have depended heavily on offline sampling and laboratory testing. Samples collected during manufacturing are analysed to understand process performance and confirm whether the product meets predefined quality specifications. The transition from offline to in-line, at-line and on-line testing is the driver for ensuring Critical Material Attributes (CMAs) and Critical Process Parameters (CPPs) are being met on a real-time basis than at the end of the product development.

Real-time release testing (RTRT) relies on sufficient process understanding and validated process information to evaluate product quality during manufacturing. When it comes to biologics, product quality is multidimensional, and many Critical Quality Attributes (CQAs) still require sophisticated analytical testing. In case of cell and gene therapies, it can involve highly variable starting materials and patient-specific manufacturing, while bispecific antibodies and other complex biologics can introduce additional process and quality-control requirements. The transition is more likely to involve increasing levels of real-time process assurance and predictive quality rather than the wholesale elimination of end-product testing. Biopharma companies and CDMOs are increasingly adopting these approaches across both upstream and downstream processes.

For example, recent studies show how Raman Spectroscopy combined with multivariate models and machine learning (ML) has been investigated to measure several parameters such as glucose, lactate, viable cell density and antibody titre during cell culture for antibody manufacturing. Here, Raman measurements and ML models are being used to estimate glucose concentrations and inform automated feeding strategies, allowing the process to remain closer to a predefined operating range. And in downstream operations, PAT provides critical information about protein concentration and selected product attributes during chromatography. In Antibody-drug conjugate (ADC) manufacturing, PAT provides greater visibility to drug-to-antibody ratio (DAR), aggregation, free payload and protein concentration where changes in these parameters can affect the product heterogeneity.

Digital bioprocessing is also extending into gene-edited cell therapies. In 2026, companies such as Cellares announced a collaboration with Stanford Medicine to expand automated manufacturing into gene-edited hematopoietic stem cell (HSC) therapies. The collaboration aims to automate manufacturing and release testing.

The growing addition of predictive layer and process control

What the predictive layer is now changing is the ability to deep dive and predict process trajectories, identify deviations earlier, perform root-cause analysis, optimise operating conditions and estimate difficult-to-measure quality attributes from combinations of process signals which was not an option previously.

Industry adoption of AI and digital twins is gaining momentum. Digital twins are moving toward more dynamic models that can provide simulations, predictions, and recommendations for process control. Predictive models can potentially identify an emerging deviation before a predefined threshold is reached. Sanofi provides an example of how historical process data can be used to establish a “golden batch” profile for manufacturing where an ongoing batch can be compared against this reference to identify process drifting and deviations from expected behavior earlier, helping operators understand when the process is moving away from desired performance.

Beyond the predictive layers lies the process control part which is changing the course of the decisions. Process models have been used extensively during process development and scale-up. But now with the digital-twin approach, the model remains more connected with the physical process through real-time or near-real-time data. This creates opportunities across process development, scale-up, tech transfer and eventually manufacturing control.

The real integration is when predictive information can be used for process control decision making and this is what is critical and will be the future for autonomous manufacturing. The European Medicines Agency's work toward Annex 22 on AI in medicines manufacturing reflects growing regulatory attention to areas including dynamic and adaptive models, model lifecycle considerations, cloud-based AI, cybersecurity and the use of AI within GMP environments, reflecting the growing need for clear frameworks governing how AI models are validated, monitored and controlled in regulated manufacturing.

Early this year in March, Roche announced that it was expanding its collaboration with NVIDIA, including the use of digital twins based on NVIDIA Omniverse libraries to optimise manufacturing processes and factory designs. WuXi Biologics launched PatroLab, a digital twin platform combining real-time process monitoring, Raman-based PAT and predictive in-silico

modeling.

Digital bioprocessing can also play an important role in addressing one of the longstanding challenges in biologics manufacturing which is transferring a process across scales, equipment and manufacturing sites. A process developed under laboratory conditions does not always behave identically when transferred to larger bioreactors, where differences in mixing, mass transfer, oxygen availability and equipment configuration can influence cell behaviour and process performance.

Even with all the ongoing developments and deployment, interoperability continues to be a challenge for digital twins. Effective digital twins require seamless exchange of information between sensors, analytical platforms, data systems, models and process-control infrastructure. Without that connectivity, digital technologies risk remaining isolated pilots rather than becoming part of routine manufacturing. The ability to scale these technologies will increasingly depend on the digital foundation underneath them.

Bioprocess data remain distributed across PAT instruments, equipment, process historians, Manufacturing Execution System (MES) and Laboratory Information Management System (LIMS) and quality systems, often in different formats and with limited contextualisation. For AI and digital twins to move beyond individual pilots, these data need to become standardised across processes and sites.

The future of increasingly autonomous bioprocesses

Digital bioprocessing is evolving from the digitalisation of individual manufacturing activities toward connected process intelligence and is further moving toward autonomous bioprocess. Connecting capabilities such as PAT for continuous process information, AI to translate data into decisions, digital twins to evaluate potential process outcomes, and advanced process control to translate these insights into manufacturing decisions creates a strong foundation for autonomous bioprocess.

The next phase of digital bioprocessing will be defined less by the adoption of individual technologies and more by how effectively they work together. However, the shift toward autonomous bioprocessing will be gradual. Challenges associated with complex biological processes, fragmented manufacturing data and interoperability issues must be addressed. In the near future, digital bioprocessing will see increasing levels of predictive quality, and automated decision support.

For biopharma companies and CDMOs, the priority will shift from isolated digital bioprocess pilots toward building an interoperable digital foundation that connects process data, analytics and control systems to build consistent quality, adaptive and intelligent biomanufacturing.

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