Bioproduction

Industry 5.0
Preparing for the future of biotechnology

Across the biotech industry, the demand for accelerated time to clinic, operational precision, and robust scalability has never been more critical. Developers face the complexity of solving a growing set of technical, operational, and regulatory challenges. In addition to meeting clinical timelines, they must manage supply chain risks, navigate increasing process complexity, and scale production without compromising quality.

Simultaneously, patients and healthcare systems are demanding broader access to advanced therapies, underscoring the necessity for cost efficiency and reliability. To address these pressures, the industry is increasingly turning to digital transformation as a strategic lever for agility, efficiency, and scalability.

As industries advance, they progressively embrace higher levels of automation, digitalization, and connectivity. This progression, termed digital maturity, reflects how organizations integrate digital systems and leverage data to drive manufacturing efficiencies. A useful framework to track this evolution is the BioPhorum

Digital Plant Maturity Model (DPMM) [1], which defines five levels of digital maturity—from manual, paper-based plants to fully autonomous, adaptive facilities (Table 1). This assessment tool can help organizations understand their digital maturity and create roadmaps for improvement, ultimately supporting the advancement of the entire industry.

Today, most facilities operate between Levels 2 and 4 in the DPMM. Industry 4.0, also known as the predictive plant, represents the current standard, characterized by digitally connected systems that enable greater efficiency and control [2]. Facilities at this stage benefit from real-time analytics, standardized equipment, and improved responsiveness, but still rely on human oversight for decision-making.

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Maturity level	Level name	Description
1	Pre-digital Plant	Manual, paper-based processes, low levels of automation
2	Digital Islands	'Islands of automation', semi-electronic records
3	Connected Plant	High levels of automation, integration, and systems standardization
4	Predictive Plant	Integrated plant network, widespread use of real-time predictive analytics
5	Adaptive Plant	'Plant of the future', autonomous, self-optimizing, plug-and-play

Table 1. The five digital maturity levels as outlined in the BioPhorum Digital Plant Maturity Model (DPMM) [1]. With each advancing level, facilities incorporate more sophisticated automation and connectivity, enhancing efficiency and integration across entire manufacturing operations.

The future lies in transitioning to the adaptive plant, also known as Industry 5.0. This is a next-generation bioproduction strategy where human-machine collaboration sits at the center. Instead of just automating manual tasks, Industry 5.0 empowers scientists and engineers with AI-enabled insights, adaptive systems, and real-time decision-making tools to optimize outcomes at every workflow stage.

Here, digital systems do more than monitor and report; they proactively optimize, adapt, and collaborate with human operators in real time. Importantly, this transition is not solely about advancing technology. It is about reintroducing the human element into the digital framework, ensuring scientific nuance and judgment remain central. This marks a fundamental shift in how we approach the future of manufacturing by combining automation with intelligence and flexibility to shape the future.

There are four critical pillars of Industry 5.0 that will make this transformation possible:

AI-predictive modeling: Applying AI and machine learning to analyze complex data sets and create reliable process models, enabling smarter decision-making during process development.

Automated process monitoring: Implementing robust, fit-for-purpose analytical technology to provide real-time insights into cell culture conditions and critical product quality attributes.

Smart manufacturing: Leveraging monitoring data to facilitate autonomous, real-time adjustments to process parameters and supporting the implementation of system-wide integration.

Long-term strategic collaborations: Forming alliances to harness collective expertise, accelerate innovation, and achieve sustainable competitive advantage, driving long-term success and industry leadership.

Collectively, this approach has the potential to reshape the future of biotech by helping developers accelerate their path from innovation to patient.

AI-predictive modeling: Transitioning from insight to foresight

Predictive modeling has long been used to simulate the effects of changing process variables, such as feed rates, temperature profiles, and pH adjustments. Traditionally, this approach has relied on empirical data from past processes, making building and maintaining these models a resource-intensive task—often requiring expert input, manual tuning, and significant experimental data.

The integration of AI and machine learning is poised to revolutionize this process. By unlocking the capabilities to analyze vast, complex datasets, AI will help scientists design more accurate, reliable, and precise models, substantially reducing development times. The ultimate goal will be models that can generalize across cell lines, processes, and even modalities—facilitating the identification of key process parameters, such as optimal media compositions, based on just a handful of predictive inputs.

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While the transformative potential of AI-informed modeling is clear, its success ultimately relies on the use of high-quality data. Clean, well-curated datasets are essential to train AI systems accurately, and while automating data cleanup will be a significant help here, human oversight remains indispensable. This oversight is crucial not only for data aggregation, curation, and contextualization, but also for validating that outputs align with real-world biological behavior.

Process monitoring: The eyes and ears of adaptive plants

Reliable, automated, and timely monitoring is the cornerstone of the adaptive plant model. Without robust, high-frequency data collection, systems cannot respond to changes with sufficient precision and accuracy. Currently, the gap between robust, automated process sensing and desired process control remains one of the largest barriers to Industry 5.0 adoption, particularly in newer, advanced modalities, such as cell and gene therapies.

Many process analytical tools, such as Raman spectrometers and capacitance probes, can be used in-line to provide timely insights into process parameters, such as cell viability, metabolite production, and nutrient consumption. However, monitoring of complex attributes including cell phenotype, protein aggregation, or post-translational modifications often relies on manual sampling and off-line analysis. This can make the analysis process both time- and labor-intensive, limiting the potential for process adjustments to be made based on real-time data.

Addressing these challenges requires the development of fit-for-purpose analytical tools and automated technologies that can deliver timely results without compromising on resolution or robustness. In particular, in-line tools designed for monitoring critical quality attributes of cell and gene therapies offer significant potential. Expanding access to state-of-the-art analytical tools—especially to smaller or resource-constrained facilities—will also be critical to the large-scale adoption of automated process monitoring and unlocking adaptive manufacturing across the industry.

Smart manufacturing: Enabling autonomous process optimization

Smart manufacturing aims to transition bioproduction away from reactive, manual processes to self-optimizing operations. In the adaptive plant model, manufacturing is conducted using a hands-off approach, where operations can be monitored and adapted remotely from a control center. Future advancements in AI and machine learning will facilitate intelligent manufacturing environments that autonomously adjust themselves in real time.

Crucially, true smart manufacturing will require both digital and physical connectivity. Linked digital systems will enable seamless data sharing across unit operations and between sites, while physical connectivity will facilitate continuous and flexible production.

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While true adaptability remains aspirational in many areas, recent advancements in modular automation, liquid handling robotics, and continuous processing are helping to realize the vision of smart manufacturing. These systems not only streamline workflows and reduce process variability but also support the decentralization of manufacturing—which is crucial for bringing production closer to the point of care.

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The value of human expertise

While AI and automation bring accelerated time to clinic and scalability, human expertise remains irreplaceable. Scientific interpretation, experimental design, and troubleshooting all depend on experienced teams who understand both the biological and operational context of their processes.

The need for curated, contextualized data underscores the central role of human judgment in training and validating AI models. Experts are also essential to integrating insights from disparate data sources and maintaining regulatory compliance regarding model transparency, traceability, and version control.

As organizations adopt more advanced technologies, many are investing in hybrid teams that combine process science, data analytics, and digital engineering. For those lacking internal resources, third-party modeling and analytics partners can provide valuable support, but internal champions remain essential to validate that solutions are fit for purpose and aligned with product goals.

Fundamentally, Industry 5.0 reinforces the principle that progress is achieved not by replacing expertise, but by empowering it with the right tools and collaborations.

Realizing the potential of Industry 5.0 with a strategic collaborator

Industry 5.0 marks the next step in the evolution of biomanufacturing. It represents a shift toward a smarter, more connected, and more collaborative approach—one that integrates AI predictive modeling, smart manufacturing, real-time monitoring, and strategic collaboration to construct a unified vision of the adaptive plant.

This model has the potential to reduce time to market, increase operational flexibility, and improve product quality, ultimately delivering therapies more efficiently and cost-effectively to patients worldwide. However, achieving this vision requires more than technology. It demands intentional design that keeps the human element ingrained at every stage—from data collection and model training to process oversight and final decision-making. Ensuring human insight remains embedded within automated systems is key to building trust, maintaining control, and driving continuous improvement.

For biotech developers, the opportunity is clear: those who embrace the transformative potential of Industry 5.0 and collaborate strategically will be well positioned to thrive in the next era of innovation and production. By choosing Thermo Fisher Scientific as your strategic collaborator, you can leverage our knowledge, resources, and innovative solutions to help you navigate the complexities of the modern biotech landscape and achieve sustainable success.

References

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