Trend 5: The rise of intelligent pharma manufacturing

- Intelligent manufacturing has arrived at the cusp of a new era, as technology advances begin to deliver smart answers to growing complexity.
- Pharmaceutical manufacturing can be personalized, efficient and dynamic.
- We expect that a convergence of intelligent manufacturing and visionary leadership will unlock value for the entire sector.

The pharmaceutical industry stands on the brink of a new manufacturing era, propelled by technological advancements in a rapidly evolving and uncertain market landscape.

In the previous decade, enterprises rushed to digitally transform their operations, creating a technology foundation that freed data and improved core business processes like scheduling and fulfillment. The pandemic and subsequent system shocks forced improvements in production flexibility and resilience, and hybrid models emerged to manage plant operations despite worker shortages and supply chain breakdowns. As life sciences leaders peer into a future of bold aspirations and huge complexity, a question arises: What role will manufacturing operations play to realize their vision and shape the future of pharma?

The answer lies in the convergence of intelligent manufacturing and visionary leadership beyond machines and materials:

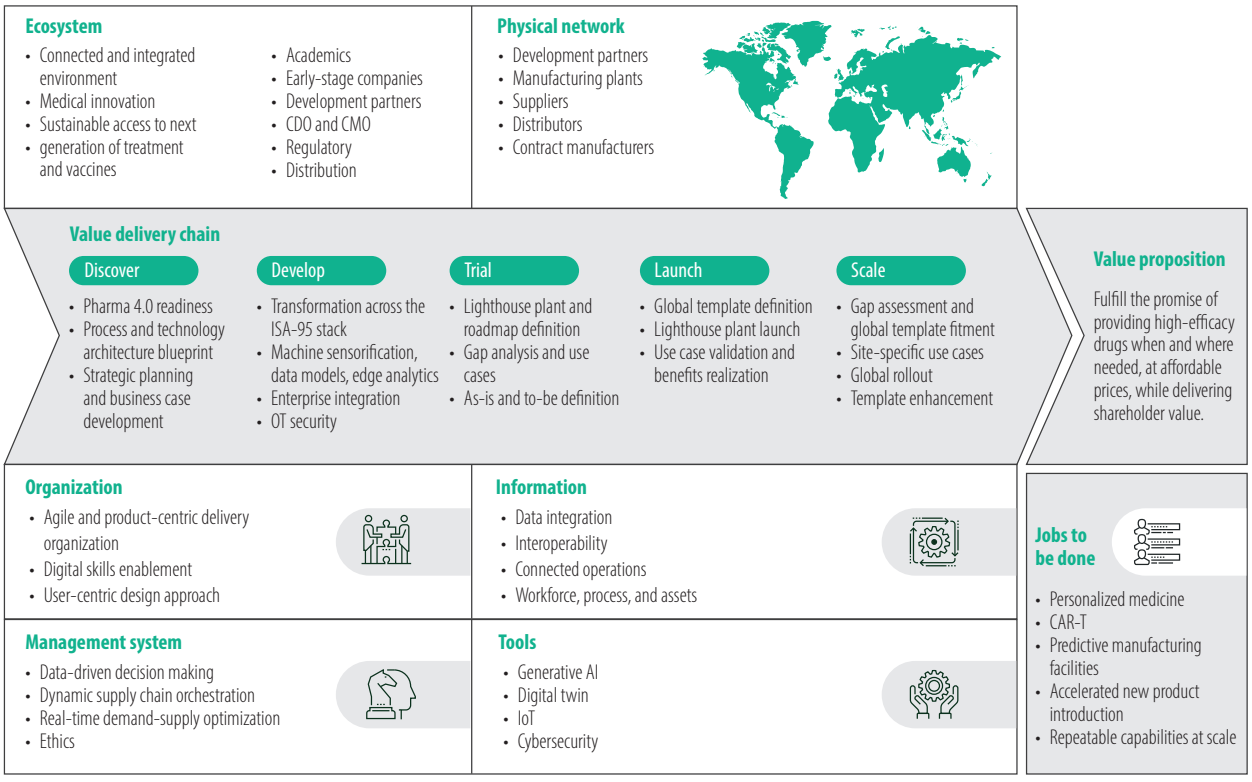
Reinvigorate the operating model, elevate humans in the age of AI, and aggressively leverage technology breakthroughs.

To unlock and create value, even a visionary manufacturing strategy requires an operating model that is up to the task. Business functions are moving to scalable platforms, corporate capabilities are shared across the industry ecosystem, and technology advancements have created step-function performance improvements. Network orchestration, talent upskilling, and rapid learning models have taken their place as essential components of the modern pharmaceutical operating model. This chapter examines how pharmaceutical manufacturing can unlock value now while taking steps to realize a vision of operational excellence for the rest of this decade.

A vision for manufacturing

How might the manufacturing operating model look? We see a profound shift toward intelligent, agile, and sustainable production operations. The smart factory is already on the rise: The global smart manufacturing market is expected to increase to $650 billion by 2029, from $277 billion in 2022.

Figure 1. Pharmaceutical manufacturing operating model



Source: Infosys Knowledge Institute

Beyond operational performance, manufacturers have an opportunity to revolutionize the way drugs are produced and delivered to patients worldwide. Through emerging manufacturing methods and enabling technologies, companies can achieve new levels of productivity, quality, and compliance (Figure 1).

Personalized medicine

Utilizing advanced analytics and genetic profiling, manufacturers will tailor therapies to individual patient needs, optimizing efficacy and minimizing adverse effects. This shift toward precision medicine requires flexible manufacturing processes capable of producing small batches of customized treatments at scale. For example, the US Food and Drug Administration (FDA) has approved several drugs tailored to genetic mutations, such as pembrolizumab for patients with certain types of tumors with specific biomarkers. Initiatives such as the US federal Precision Medicine Initiative promise to accelerate the adoption of personalized medicine, largely through the collection and analysis of medical data.

Advances are also occurring in precision therapies such as CAR-T (chimeric antigen T-cell receptor) treatments, which are tailored to individual patients. These breakthrough gene therapies treat or cure genetic diseases, diabetes, and blood disorders. A study of 54 patients with hemophilia B found that 51 did not require prophylactic treatment three years after being treated by gene therapy.

These drugs are manufactured in small batches and to the highest safety and accuracy standards. However, the cost of these therapies has limited their potential so far. In the US, CAR-T therapy costs $400,000 per dose, largely because of manufacturing costs. Other gene therapies can cost as much as $4.3 million per dose. Fortunately, Indian pharma company ImmunoACT is manufacturing a new CAR-T therapy called NexCAR19 that is expected to cost $50,000, an encouraging step to make these treatments more widely available.

Digital twin technology

Digital twin technology is revolutionizing pharmaceutical manufacturing by enabling

> “Intelligent manufacturing will help bring flexibility in manufacturing, better quality, improved productivity, and provide customization at scale. It will allow companies to produce personalized medicines at much higher quality.”
>
> **Prabhat Kaul**
> Vice president, Infosys Life Sciences

virtual experimentation and predictive modeling. Manufacturers simulate production processes in real time, optimizing parameters and identifying potential issues before they occur.

Virtual manufacturing environments serve as testbeds for innovation, accelerating the development and deployment of new drugs and formulations.

Pharmaceutical companies leverage digital twins to simulate production processes, optimize equipment performance, and predict outcomes. For example, Sanofi used virtual twins to simulate manufacturing systems prior to implementation and to refine production processes before deploying them. This enabled Sanofi to accelerate the timeline to launch its new vaccine manufacturing plants.

Continuous manufacturing

Traditional batch-based manufacturing will give way to continuous manufacturing systems that offer new levels of efficiency, flexibility, and cost-effectiveness. Continuous processes will enable real-time monitoring and control, reducing time to market and minimizing waste. By integrating upstream and downstream operations, manufacturers will streamline production processes and enhance product quality and consistency — vital for new precision medicines.

Pfizer, Vertex Pharmaceuticals, and others have implemented continuous manufacturing processes for some drugs, reducing production time and improving product quality. Experts also predict that switching to continuous manufacturing plants will decrease production facility size by as much as 70%.

Regulatory agencies are also encouraging the adoption of continuous manufacturing through initiatives like the agency's Emerging Technology Program. Research into continuous manufacturing in the US found no significant regulatory barriers, and the accelerated time to market provided an estimated $171 million to $537 million in additional revenue for pharma companies.

Data-driven decisions

Data is at the heart of pharma manufacturing, driving informed decision making and process optimization. Large language models will come and go, but enterprise data and knowledge will always be valuable. Advanced analytics and machine learning will unlock insights from vast datasets, meaning manufacturers can enhance productivity, quality, and compliance.

Data-driven decision making will lead to innovative business models:

1. **Dynamic supply chain orchestration.** Companies use real-time data and AI to optimize their supply chains, allowing them to adapt rapidly to market changes and minimize disruptions while reducing inventory costs.

2. **Real-time demand-supply optimization.** The new model enables "buy anywhere, ship anywhere" for

distributors, providing a consistent customer experience, optimizing warehouse resources, and boosting sales team productivity.

Companies such as Merck and Novartis have invested in data analytics platforms to analyze manufacturing data, identify trends, and optimize production processes.

Regulatory innovation

Regulatory agencies will embrace agile and risk-based approaches to oversight, fostering innovation and accelerating time to-market for new therapies. Collaborative frameworks and regulatory sandboxes will allow manufacturers to pilot emerging technologies and novel manufacturing processes in a controlled environment.

Regulators will prioritize patient safety while fostering a culture of innovation and continuous improvement within the industry. The European Medicines Agency has already created an Innovation Task Force. This will "invite anyone with a new idea to come to us, talk about it and we try to advise as to what the right path is," says Emer Cooke, the agency's director general.

In addition, the FDA's Quality Metrics Initiative advises companies on how to measure and improve manufacturing processes and product quality. Regulatory sandboxes, such as the FDA's Digital Health Software Precertification (Pre-Cert) Pilot Program, provide a framework for piloting innovative technologies in a way that complies with regulatory frameworks.

Robust frame for innovation

To realize this vision, companies must take full advantage of emerging pharmaceutical manufacturing technologies, such as generative artificial intelligence (AI), the internet of things (IoT), advanced analytics, and cloud computing.

Growth in these areas is significant; the industrial automation market alone is projected to be worth $115 billion by 2025. Companies already spend heavily on nanotechnology and industrial robotics, with both areas growing at a rapid pace.

The UK's Centre for Process Innovation is working with pharma giants to create a cloud-first factory at its Medicines Manufacturing Innovation Centre in Scotland.

The public–private collaboration plans to use emerging technologies to reduce the operational cost of pharmaceutical manufacturing by as much as 30% and increase productivity by 50%.

Each emerging technology augments one another, creating not just a foundation for smart manufacturing but also a robust frame to build upon.

Generative AI drives advances

Generative AI algorithms will revolutionize drug discovery and formulation by generating novel molecular structures and predicting their properties. Machine learning models will analyze datasets of billions of chemical compounds, accelerating

the identification of promising drug candidates and optimizing formulation parameters. Analysts project that AI in drug manufacturing will grow at a nearly 46% compound annual growth rate to reach $20.8 billion by 2028.

Generative AI algorithms are revolutionizing drug discovery and development by accelerating the identification of promising drug candidates. For example, companies such as Atomwise and Insilico Medicine use AI algorithms to design novel molecules with desired properties, expediting the drug discovery process. Furthermore, collaborations between pharmaceutical companies and AI startups are becoming increasingly common, highlighting the industry's interest around AI in drug discovery and manufacturing.

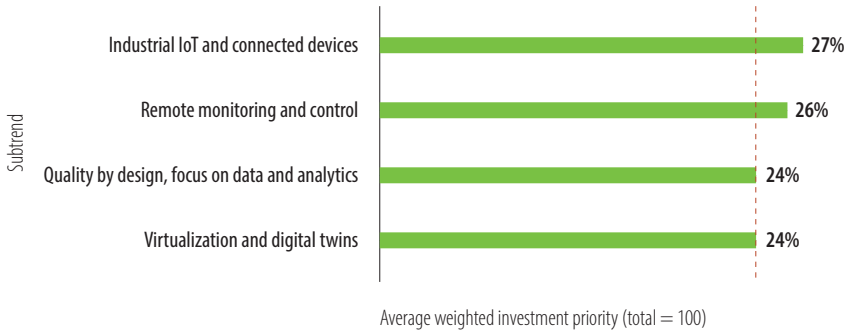
IoT devices to connect data

Biomanufacturing processes are complex, making it difficult to implement robust analytical control infrastructure. IoT devices are ideal for connecting contemporary physical-world data with the infinite data storage and processing capabilities available in the cloud.

For example, companies such as Pfizer and GSK use IoT sensors to collect data on temperature, humidity, and pressure in manufacturing facilities, enabling real-time monitoring and control.

Infosys Knowledge Institute research found that IoT was a top pharma investment priority (Figure 2). Platforms such as PTC's ThingWorx provide connectivity and analytics capabilities tailored to e pharmaceutical industry. Beyond optimization and product quality, IoT-enabled packaging and labeling tracks inventory across manufacturing, transportation, and storage. IoT devices enable monitoring of equipment performance, reducing unplanned shutdowns and production issues.

Figure 2. IoT and connected devices are top investment priority in life sciences



Note. Percentages do not total to 100 due to rounding.

Source: Infosys Knowledge Institute

For example, Novartis uses IoT and AI for predictive maintenance to reduce downtime in their supply chain.

Additionally, IoT devices will be valuable for regulatory compliance. The data collected will support compliance by tracking conditions throughout the manufacturing process.

Data integration

The pharma industry has not made the most of supply chain collaboration thus far, but as contract manufacturing drives more advanced collaboration models, data integration and interoperability will make collaboration and information sharing across disparate systems and stakeholders easier.

Open standards and interoperable platforms enable secure data exchange, boosting innovation and collaboration. Efforts such as the Pharmaceutical Supply Chain Initiative promote data sharing and interoperability standards among pharmaceutical companies and suppliers.

Enterprise software has a role to play as well, as platforms like SAP's Integrated Business Planning for Supply Chain enable data integration and collaboration across partners.

Essential cybersecurity

No matter how attractive the potential benefits of collaboration, cybersecurity measures will be essential to protect manufacturing operations from threats and to ensure data integrity and confidentiality.

Cybersecurity in operational technology is a challenge for every industry. Legacy devices, embedded proprietary software, and 24/7 operations make managing security a challenging task. In pharmaceuticals and medical device manufacturing, managing these challenges properly is even more important thanks to the higher regulatory requirements attached to sensitive personal information and the concurrent risks to patient safety and personal information. Cybersecurity measures include encryption, access controls, and intrusion detection systems to ensure privacy and integrity for data assets. Valuable data ranges from intellectual property worth billions of dollars to personal medical information.

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> **David De Cremer, Gary Kasparov**
> Harvard Business Review

Concerns about cyberthreats have discouraged some pharma companies from pursuing advanced technology — fearing that each new element increases the attack surface. Some pharma firms have avoided digital twin technology, worrying that digital models of their manufacturing facilities and processes could be stolen.

Ethical considerations

As pharmaceutical manufacturers harness the power of advanced technologies, they must also address ethical considerations surrounding data privacy, security, and algorithmic bias.

Robust data governance frameworks and ethical guidelines ensure responsible data and AI use, safeguarding patient privacy and upholding ethical principles.

Regulatory frameworks such as the EU's General Data Protection Regulation and the US Health Insurance Portability and Accountability Act mandate strict guidelines for the collection, storage, and use of patient data. Organizations such as the Partnership on AI and the IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems are developing ethical guidelines for AI development and deployment.

The new skills needed

The journey to intelligent manufacturing is well under way, marked by both incremental advances and transformative initiatives across the pharmaceutical landscape. However, this potential will be realized only if workers with the relevant skills are readily available.

As manufacturing becomes more digital, companies need workers with new skills beyond traditional production. Intelligent factories need employees who understand pattern recognition, algorithms, and statistics so they can assess, analyze, and manage data that must be shared and used.

Manufacturing faces a massive skills shortfall for the rest of this decade, as a projected 2.1 million of 4 million manufacturing jobs could go unfilled. Many of these shortages relate to wider labor trends, such as a lack of data scientists and analytical competencies. While remote working increases the potential talent pool, it also increases demand for those collaboration skills as they work at a distance from physical plants and from each other.

The industry is experimenting with creative new ways to address its growing skills shortage. In the UK, the University of Birmingham is leading a training initiative that is virtual reality-enabled, giving students a realistic experience of manufacturing work. It also includes training in data and analytics, AI, and other digital skills.

As new technologies have become established, manufacturing has evolved beyond human-to-machine collaboration to machine-to-machine collaboration. However, machines should augment, not replace human involvement, and they can increase worker effectiveness.

David De Cremer of Northeastern University and chess legend Garry Kasparov make

the case that AI and authentic intelligence are complementary, rather than opposites. They argue that the intuitive, emotional, and culturally sensitive abilities of humans are needed, as is AI speed, accuracy, and rationality. "The question of whether AI will replace human workers assumes that AI and humans have the same qualities and abilities — but, in reality, they don't," they wrote in Harvard Business Review. A vision for intelligent manufacturing offers leaders a way to navigate a complex and demanding operational landscape. Pharmaceutical manufacturing technology may provide the tools, but humans and their continuously evolving skills will be needed to achieve the industry's full potential and shape a brighter future for patients and society.