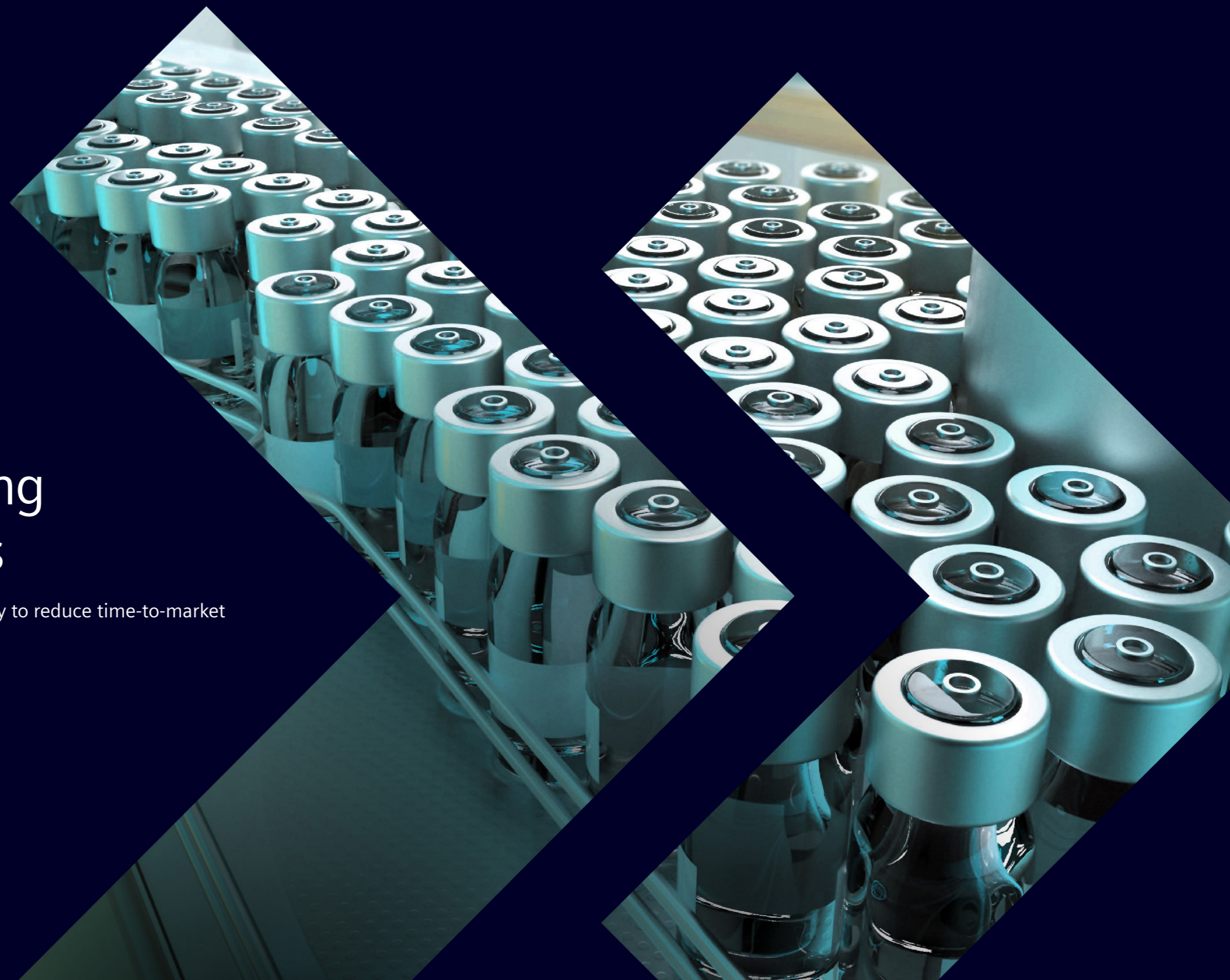


DIGITAL INDUSTRIES

Smart Manufacturing for Pharmaceuticals

Build a proactive, long-term manufacturing strategy to reduce time-to-market

[siemens.com/pharma](https://www.siemens.com/pharma)



Overcome barriers to achieve operational efficiency

Today, the increasing demand for pharmaceuticals means that companies are competing to deliver new and existing therapies faster and at scale to the world's growing and aging population.

Challenges include mounting cost pressures, maximizing revenues during the patent protection period and quickly responding to fluctuations in demand. These challenges require drug manufacturers to accelerate time-to-market. And, while outsourcing your manufacturing plan might sound attractive in the short term, it can also pose systemic risks related to cybersecurity, traceability and compliance.

According to a McKinsey study, you can reduce your baseline cost by 10-20 percent with a proactive, smart manufacturing strategy that addresses quality, compliance and supply chain vulnerabilities without the risks associated with outsourcing. A survey conducted by ORC International found that it's essential to speed up market launch because any delay can cost you as much as \$15 million per day. Avoiding these delays becomes critical as raw material prices have reached unprecedented levels that greatly impact margins. Unforeseen delays, low efficiencies and manual processes can also become major roadblocks. Navigating the uncertainty of final drug approval means that your timeline can be hard to pin down. The ability to produce at scale and adjust production rapidly on demand is critical to your success.

Faced with these challenges, how can you maximize operational readiness and efficiency – from high volume to personalized production – without compromising quality?

To maintain a competitive advantage, you must adopt an end-to-end manufacturing approach by integrating real-world data with a comprehensive digital twin to increase the flexibility of your plant and manufacture products faster and at scale – all while keeping quality under control.

Siemens Smart Manufacturing for Pharmaceuticals offers digital and automation solutions to help pharma companies:

- Speed up process and plant engineering
- Ensure right-first-time manufacturing within required specifications
- Meet production targets and drive continuous improvement

By deploying the digital thread for smart manufacturing, you can deliver life-saving products to patients faster and more sustainably, while also maximizing operational efficiency and gaining significant cost savings to achieve greater business resilience.

Pharmaceutical manufacturing drivers

- Pace of innovation: Increasing competition is driving the need to speed up time-to-market.
- Tight margins: Due to the rising cost of raw materials, it's essential to implement technology that can reduce costs without sacrificing quality.
- Diverse and increasingly complex portfolios: It's important to achieve operational excellence and increase flexibility, while also ensuring affordability of new drugs.
- Scale of production: Adaptability is key to meeting increases in demand and producing at scale, from high-volume to personalized production.



Adopt an end-to-end approach to operations

Compared to other industrial sectors, the pharmaceutical industry still shows potential for significant improvement in its leveraging of digital and automation technologies. It's a fact that existing reactive manufacturing planning and traditional approaches for implementing production systems cannot supply the flexibility and speed necessary to thrive in today's competitive landscape.

By choosing to accelerate your digital transformation with Siemens Xcelerator, our open digital business platform, you'll be equipped with three key solutions to maximize revenues during the patent protection period and seize new market opportunities before your competitors do.

1. Speed up process and plant engineering

Pharmaceutical manufacturers must learn to be agile in the midst of increasingly diverse product portfolios, various production scales and complex new therapies.

In order to scale and optimize processes in advance, manufacturers can leverage a production digital twin of the entire pharmaceutical manufacturing process, production lines and equipment. With a modular production setup, pre-validated equipment seamlessly plugs into the line allowing production to continue with minimal disruption in the event of machine failure or product changeover. Adopting an integrated modular plant design through the "plug and produce" of equipment with reliable "no programming" diagnostics brings improved operation and maintenance throughout engineering, and from concept to design. Moreover, you can ensure reliable commissioning while reducing testing effort and start-up time. As such, virtual operator training systems can be built to train people in a comfortable office environment before the actual line is connected.



2. Ensure right-first-time manufacturing

Deploying more flexible and paperless manufacturing practices will help you address production complexity and variability without sacrificing quality and profitability. The system coordinates in real-time to synchronize and exchange parameter values, materials, operations and equipment. This process better accommodates product changeover and production scales to ensure right-first-time manufacturing. By enabling a more detailed recording of process data, conditions and results, paperless manufacturing helps you build error-resistant processes that are more robust and less prone to deviations. Once in place, you can manage execution, then the review and release of electronic batch records (eBR). This method allows for every step and every material to be monitored, tracked and recorded during production.

Ultimately, integration between enterprise resource planning (ERP), manufacturing execution system (MES), distributed control system (DCS), supervisory control and data acquisition (SCADA) enables you to gain a holistic view of production processes and increases user efficiency.



One of the main advantages of eBR is the integration between the control system and the MES system that brings the control data directly into the manufacturing guides in real time. As a result, more than 530 manual entries from operators have been removed, ensuring data integrity, and simplifying the process.”

Nina Mikadze, Systems and Compliance Manager, AGC Pharma Chemicals





3. Meet production targets and drive continuous improvement

Manufacturers are increasingly using the potential of IoT, edge technology, machine learning and analytics to automatically monitor operations. This allows direct access to intervene on operational processes from anywhere, securely and without installation effort, to ensure product quality. You'll leverage historical and real-time data to consistently meet throughput, quality and sustainability targets.

Combining operational data with your digital twin allows for predictive and prescriptive analytics that enables full visibility of your manufacturing operations. Insights will result in:

- Potential improvement scenarios that allow you to efficiently and rapidly address deviations during operations, and increase your right-first-time ratio
- Production process innovation measures, such as the usage of industrial-grade artificial intelligence (AI)
- Transparent, real-time production data on performance, quality and sustainability KPIs (i.e. energy efficiency, resource efficiency and circularity)



Thanks to the smart networking of machines and processes, production at the Pfizer plant in Freiburg can be faster and more flexible and can better conserve resources.”

Gunther Bechmann PhD, Senior Manager Operations, Manufacturing, Pfizer

Manufacture life-saving products faster and at scale

Smart Manufacturing for Pharmaceuticals helps rapidly develop fully integrated and sustainable engineering and production processes. Moreover, pharma companies can leverage operational insights to continuously improve operations and build a proactive, long-term manufacturing strategy.

Siemens Smart Manufacturing solution includes interoperable, flexible, open hardware and software, a comprehensive digital twin, IT/OT integration, machine standardization, cybersecurity, consulting services and deep industry expertise. Let us show you how it can help your organization.



Siemens Digital Industries (DI) is an innovation leader in automation and digitalization. In close collaboration with partners and customers, DI drives the digital transformation in the process and manufacturing industry. With its Digital Enterprise portfolio, Siemens offers companies of all sizes end-to-end products, solutions and services for the integration and digitization of the entire value chain. Optimized for the specific requirements of each industry, the unique portfolio enables customers to increase their productivity and flexibility. DI is continuously expanding its portfolio through innovations and the integration of future technologies. Siemens Digital Industries is headquartered in Nuremberg and employs around 72,000 people worldwide.

For more information on Siemens Smart Manufacturing for Pharmaceuticals, visit [siemens.com/pharma](https://www.siemens.com/pharma) or follow us on [LinkedIn](#).

© Siemens 2023. A list of relevant Siemens trademarks can be found [here](#).

Other trademarks belong to their respective owners.