SIEMENS

DIGITAL INDUSTRIES

Smart manufacturing for pharmaceuticals

Make your production sites adaptable and more efficient while ensuring consistent quality

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Urgent challenges in the pharmaceutical industry

Pharmaceutical companies must remain competitive, not only against other pharma companies, but against the ailments, illnesses and conditions that hurt patients who need lifesaving medications and therapies. Amid the influx of new technologies, the pharma industry still struggles to quickly adapt to changing market demands and adopt new manufacturing processes on legacy manufacturing lines.

The industry faces rising demands to produce increasingly complex therapies and diverse drug product portfolios, all while margins continue to tighten. Uncertainty in this changing environment makes agility essential for rapid ramp-up or seamless production adjustments. However, navigating the uncertainty of final drug approval makes timelines hard to pin down and can negatively impact the time a pharma company has to maximize revenue before a generic alternative hits the market.

Producing at scale and providing drugs and therapies that meet stringent quality standards is a massive, expensive and time-consuming undertaking under the best of circumstances.

Evolving patient demographics, innovative product types, intensified regulatory scrutiny, and performance pressure all contribute to the challenges the pharma industry faces today. To remain competitive and effectively meet healthcare needs, pharmaceutical companies emphasize the need for speed, efficiency, agility, and sustainability, all while keeping quality under control.

How can today’s pharmaceutical companies make their production sites future-ready and stay ahead in the race against time? How can they ensure continuous availability of essential therapies for patient care?

Increasingly complex production landscape

Anticipating production needs in the pharmaceutical industry is challenging due to uncertainty related to several interconnected factors, which include:

Unpredictable outcomes of clinical trials and drug approval timeline

Demand fluctuations and evolving patient needs that add complexity to scheduling brownfield and greenfield projects

Quality risks associated with tech transfer and scale-up

Inconsistent, manual manufacturing processes and equipment malfunctions that can compromise drug product quality

In addition, compliance and traceability requirements further complicate matters as companies must continuously adjust to meet stringent regulatory standards, which in turn leads to increased costs and unexpected delays.

Also, suboptimal consumption of raw materials, water, and energy can raise production costs and environmental impact. Finally, the industry faces growing cybersecurity threats, which can jeopardize drug product safety and expose sensitive intellectual property or patient data.

Untapped potential of digitalization in pharma manufacturing

Digitalization has emerged as one of the most effective ways to ensure regulatory compliance and quality, while also increasing production agility and cost efficiency. However, despite the advancements in pharmaceutical manufacturing technology, there continues to be significant room for improvement:

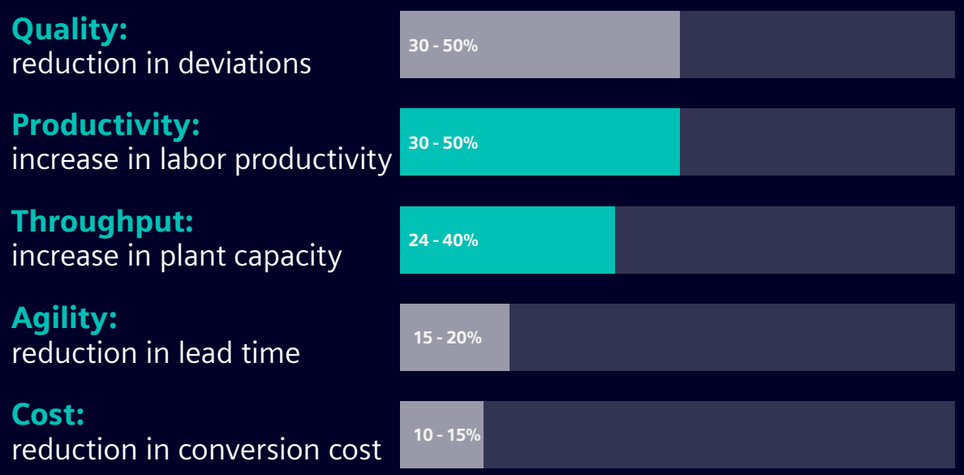
35%
overall equipment efficiency currently in pharma due to poor equipment management[1]

19%
pharma professionals who have partially employed AI in manufacturing operations[2]

50-100%
potential improvement of OEE by using AI to increase equipment speed while adjusting critical machine settings, material specifications, and operator procedures[2]

31%
projected CAGR of the digital twin technology in pharmaceutical manufacturing from 2024-2034[3]

Expected impact of digitalization



Source: McKinsey

The strategies that worked in the past are no longer viable. The pharma companies of tomorrow must prioritize building robust, cost-efficient, and sustainable manufacturing processes.

What's needed is a digitalization setup that enhances the readiness, efficiency, and responsiveness of production operations. Digitalization is key to unlocking next-generation pharmaceutical manufacturing operations.

Industry proof points of realized benefits

- 8 to 12%
engineering savings[4]

- 50%
conversion time for brownfield project[5]

4,000 data tags
extracted in real time[6]

3 - 6 weeks
to model all automation processes[7]

- 80%
time and effort for MES integration[7]

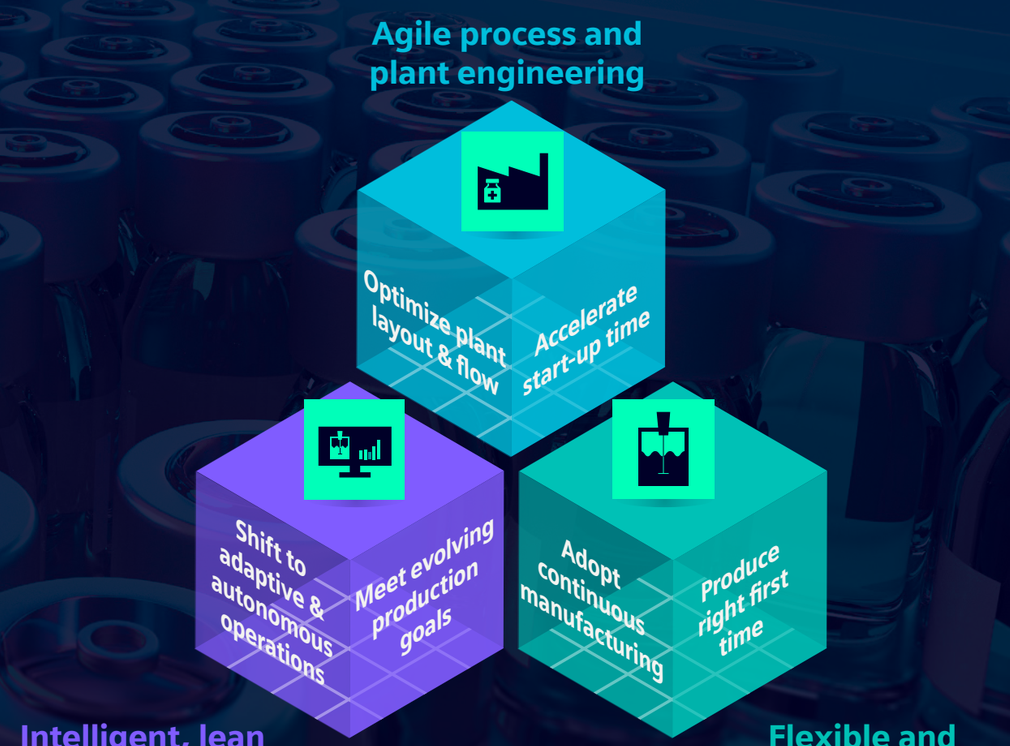
+ 40%
more energy-efficient plant[8]

Sources: 4 Novartis | 5 BioNTech | 6 AGC Pharma Chemicals | 7 Bayer Bitterfeld | 8 Pfizer

Taking a **smart manufacturing approach**

Digitalization allows pharmaceutical manufacturers to take a comprehensive smart manufacturing approach that will significantly enhance operations and give them the ability to quickly adapt to changing market demands without compromising quality.

Siemens has identified three key imperatives the pharmaceutical industry should focus on to navigate uncertainty and turn manufacturing complexity into a competitive advantage.



1. Agile process and plant engineering

Agile process and plant engineering prepares companies to face uncertainties associated with final drug approval and demand fluctuations. It gives users the tools to anticipate and accelerate operational readiness:

- Streamline interdisciplinary collaboration on primary and secondary manufacturing processes
- Enable efficient, integrated engineering and ensure data integrity throughout the plant lifecycle
- Validate and optimize processes using a digital twin
- Deliver greater versatility and minimize start-up time with standardization in automation

The digital twin is more than just a visualization. It enables the ability to explore various possibilities through simulation:

- Virtually verify the system before investing
- Design and optimize the plant layout to maximize efficiency and productivity
- Streamline processes by identifying bottlenecks and optimizing material flow
- Use what-if analysis to explore countless scenarios to make informed decisions
- Validate and virtually commission production lines, reducing errors and downtime

The digital twin enables scenario testing, resource allocation, and throughput improvement. This agile approach allows scalability for varying production demands, and optimizes facility layouts, energy use, batch sizes and sequences, accelerating time-to-market and ensuring cost-efficiency, quality, and sustainability.

Additionally, standardization, modular automation, and virtual validation of your process helps minimize start-up time. Virtual commissioning can reduce testing effort and enable early operator training in a realistically simulated environment.

Finally, implementing a comprehensive cybersecurity strategy with multiple layers of defense ensures your production is safeguarded against cyber threats.

- **System integrity:** Regularly update and harden your systems, adopt strong authentication and access control, and ensure secure communication between IT and OT environments
- **Network security:** Segment your networks to isolate and protect critical assets, use firewalls and VPNs to secure network traffic, and provide secure methods for remote access
- **Plant security:** Ensure physical access protection for authorized personnel only, implement and enforce robust security policies, and continuously monitor systems to detect and respond to threats promptly

An agile plant and process engineering approach significantly accelerates the engineering of the production plant, from design to commissioning, by enabling holistic data usage across all project stakeholders and disciplines.

2. Flexible and paperless manufacturing

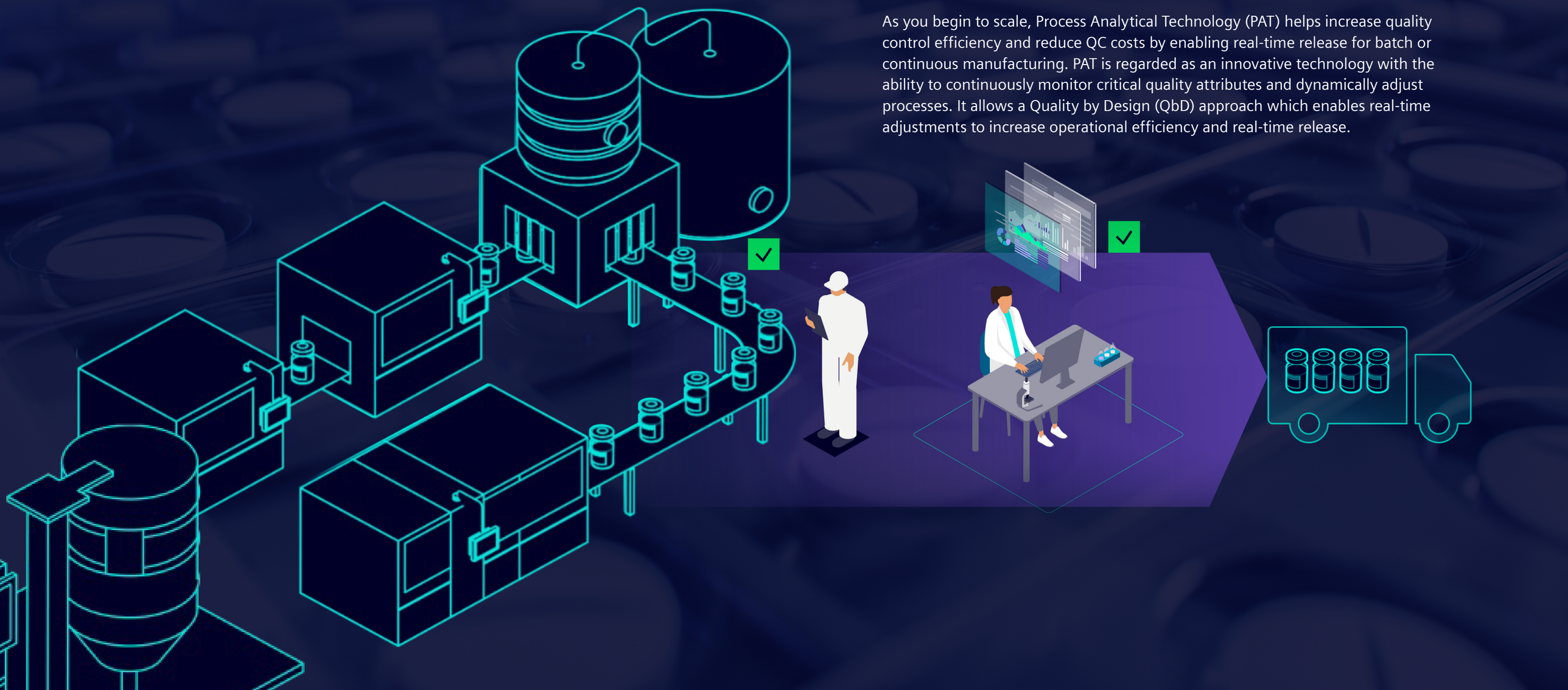
Deploying flexible and paperless manufacturing practices will allow companies to maximize operational efficiency by maintaining data integrity, ensuring traceability across the plant, and producing right first time. Manufacturers will be able to meet the diverse needs of pharmaceutical primary and secondary manufacturing, from personalized medicine to high-volume batch and continuous production.

One way to remain flexible amid uncertainty is by adopting modular plant design. This enhances flexibility by allowing pre-validated equipment to be seamlessly integrated into the line in case of machine failure or product changeover, ensuring production continues with minimal disruption.

Manual operations are traditionally guided and recorded on paper. This can be lost, difficult to read, falsified, and time-consuming to review. By enabling a more detailed recording of process data, conditions and results, paperless manufacturing helps build error-resistant processes that are more robust and less prone to deviations. Utilizing electronic batch records (eBR) allows for review by exception and enables the expedited release of products based on real-time testing data.

The right scalable solution for paperless manufacturing, from paper on glass to fully integrated shopfloor production systems, can grow with the needs of the company, providing additional benefits through new functionalities while building on the existing advantages. This scalable approach helps manage the scope, user adoption, implementation complexity, and cost.

As you begin to scale, Process Analytical Technology (PAT) helps increase quality control efficiency and reduce QC costs by enabling real-time release for batch or continuous manufacturing. PAT is regarded as an innovative technology with the ability to continuously monitor critical quality attributes and dynamically adjust processes. It allows a Quality by Design (QbD) approach which enables real-time adjustments to increase operational efficiency and real-time release.

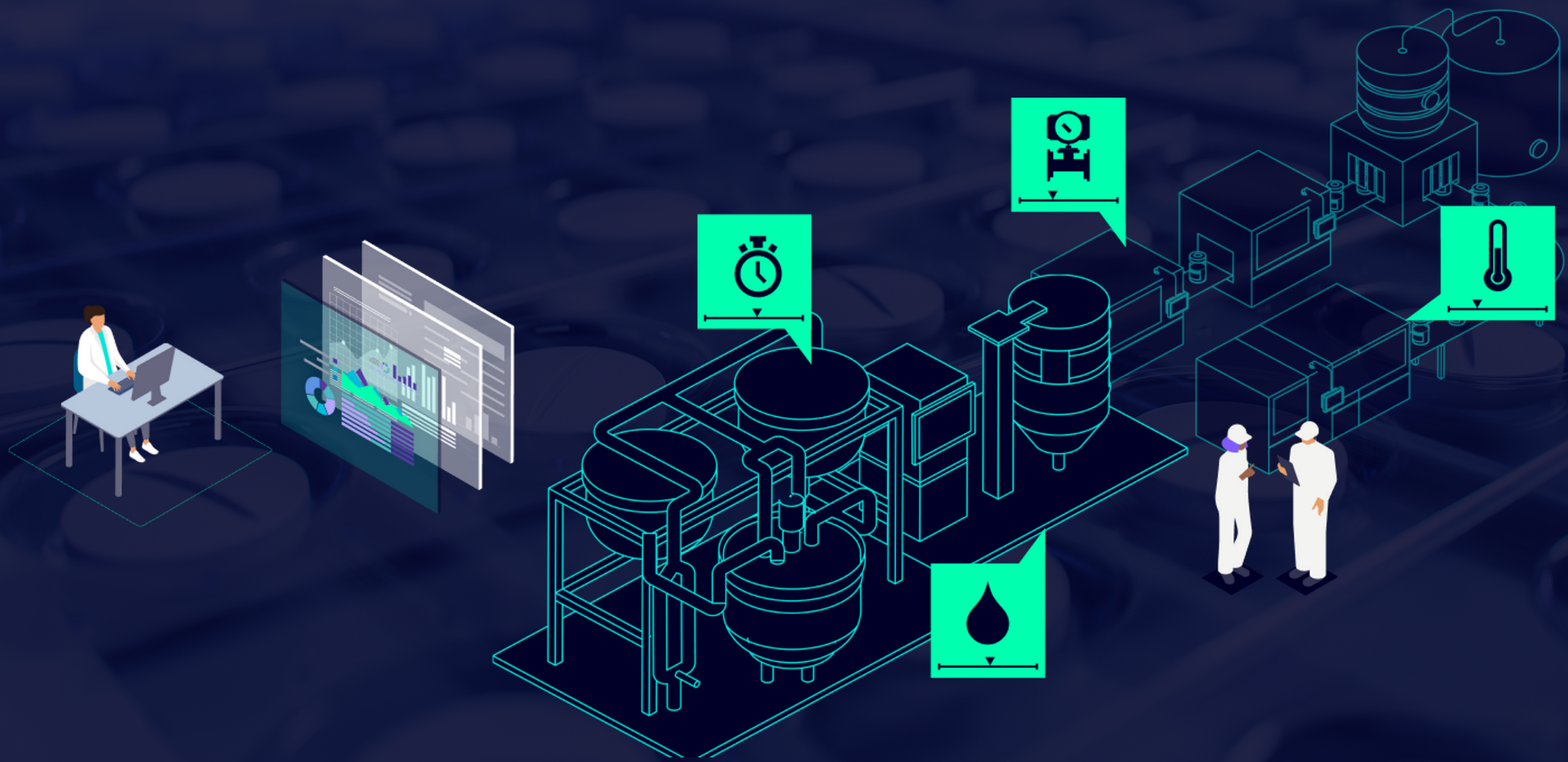


3. Intelligent, lean and sustainable operations

With an intelligent, lean and sustainable operations approach, pharma manufacturers can make a strategic shift from automated to predictive, adaptive, and autonomous operations that meet production, quality, and sustainability targets, while continuously driving efficiency and aligning with GMP and regulatory standards.

This approach emphasizes the importance of IT/OT convergence to seamlessly connect information and operations and leverages analytics, AI, machine learning, the Internet of Things (IoT), edge computing, and the cloud.

Intelligent operations can collect, harmonize, and display data for actionable predictive insights with real-time monitoring. This will enhance operational responsiveness by enabling users and stakeholders to predict issues, continuously adapt to changes, and make data-driven decisions. You'll achieve near real-time monitoring, full operational transparency, and predictive insights tailored to your organization and KPIs.



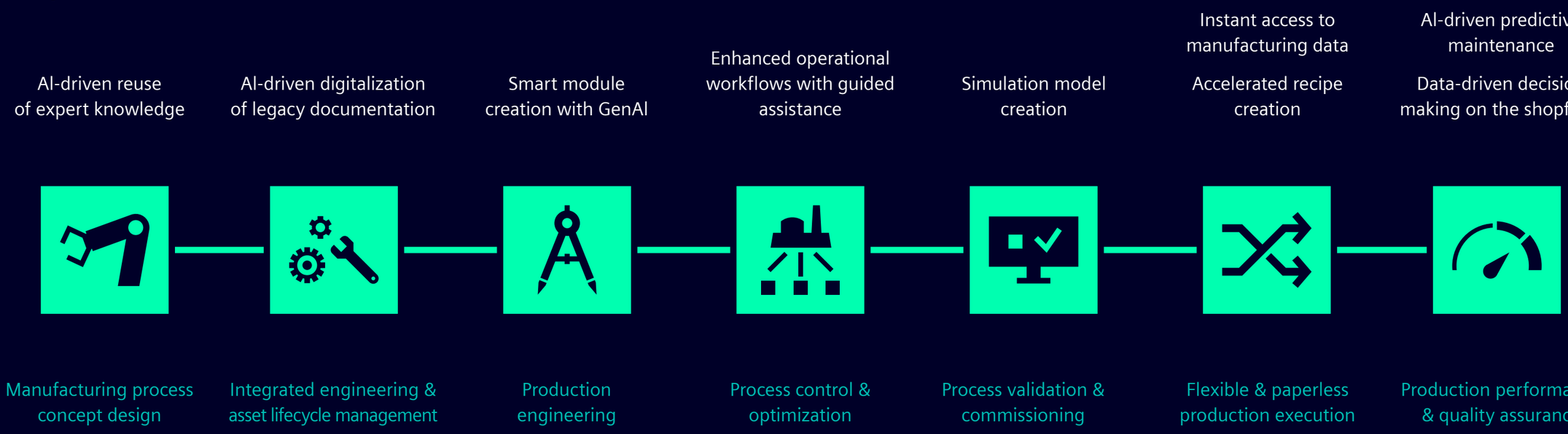
AI-powered smart manufacturing for pharmaceuticals

Despite the significant advantages AI offers when integrated into engineering and manufacturing, many pharmaceutical companies remain hesitant to implement AI at scale.

Overcoming this gap between potential and adoption will be critical for the future of pharma manufacturing. Siemens' smart manufacturing solution for pharmaceuticals support various AI-enabled use cases, helping drive efficiency and achieve performance, quality, and sustainability targets.

Our vision of Industrial Copilots along the entire value chain is designed to unlock the potential of generative AI to improve human-machine collaboration and accelerate innovation cycles.

Examples of AI-enabled use cases



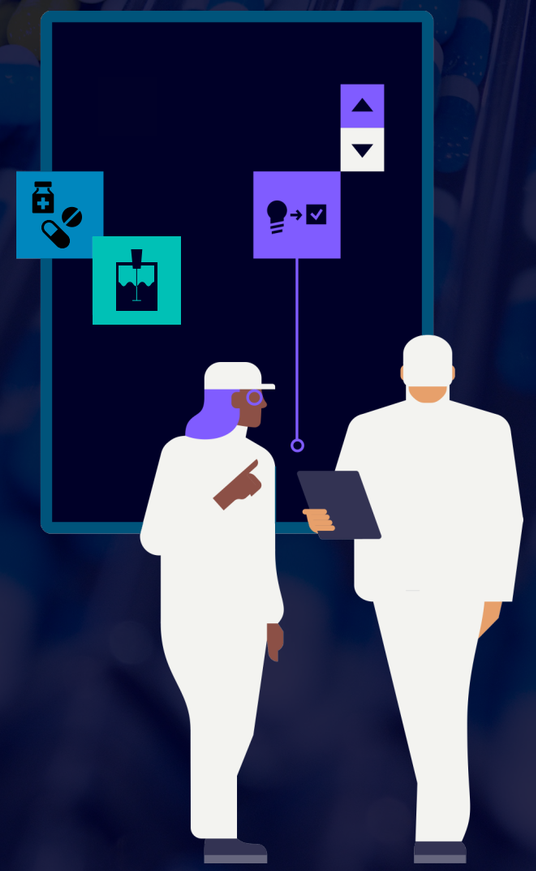
Siemens' **smart manufacturing** solution **for pharmaceuticals**

How can pharmaceutical companies prepare for uncertainty and ensure continuous availability amid an increasingly complex production landscape? How can they ensure that they don't experience drug shortages that impact the most vulnerable patients?

By taking a comprehensive smart manufacturing approach to their operations, pharmaceutical manufacturers can accelerate operational readiness by rapidly implementing virtually developed, integrated, and sustainable production processes. This approach maximizes operational efficiency and flexibility, preparing companies to face growing cost pressures and regulatory constraints for increasingly diverse and complex drug product portfolios. With these solutions, companies can receive actionable insights and have the ability to make data-driven decisions to meet production, quality and sustainability targets and continuously drive efficiency.

With Siemens Xcelerator portfolio, an open, easy and flexible business platform, pharmaceutical manufacturers will have the most comprehensive portfolio featuring adaptable and modular automation solutions, seamlessly integrated with interoperable software and expert services for pharmaceutical manufacturing. Siemens' smart manufacturing solution for pharmaceuticals encompasses all stages of primary and secondary pharmaceutical manufacturing, from engineering through execution and production optimization.

With a strong ecosystem of partners, Siemens covers the digital transformation needs across the full end-to-end value chain ensuring you're prepared to transition from automated to adaptable and sustainable pharmaceutical production and manage the complexities and uncertainties without sacrificing efficiency, scalability or quality.



References:

1. **McKinsey:** Operations can launch the next blockbuster in pharma
2. **Roland Berger:** Future of health 6 - The AI (r) evolution in health
3. **Globe Newswire:** Digital Twin Technology in Pharmaceutical Manufacturing market is projected to grow at a CAGR of 31.3% by 2034: Visiongain

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-manufacturing.

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