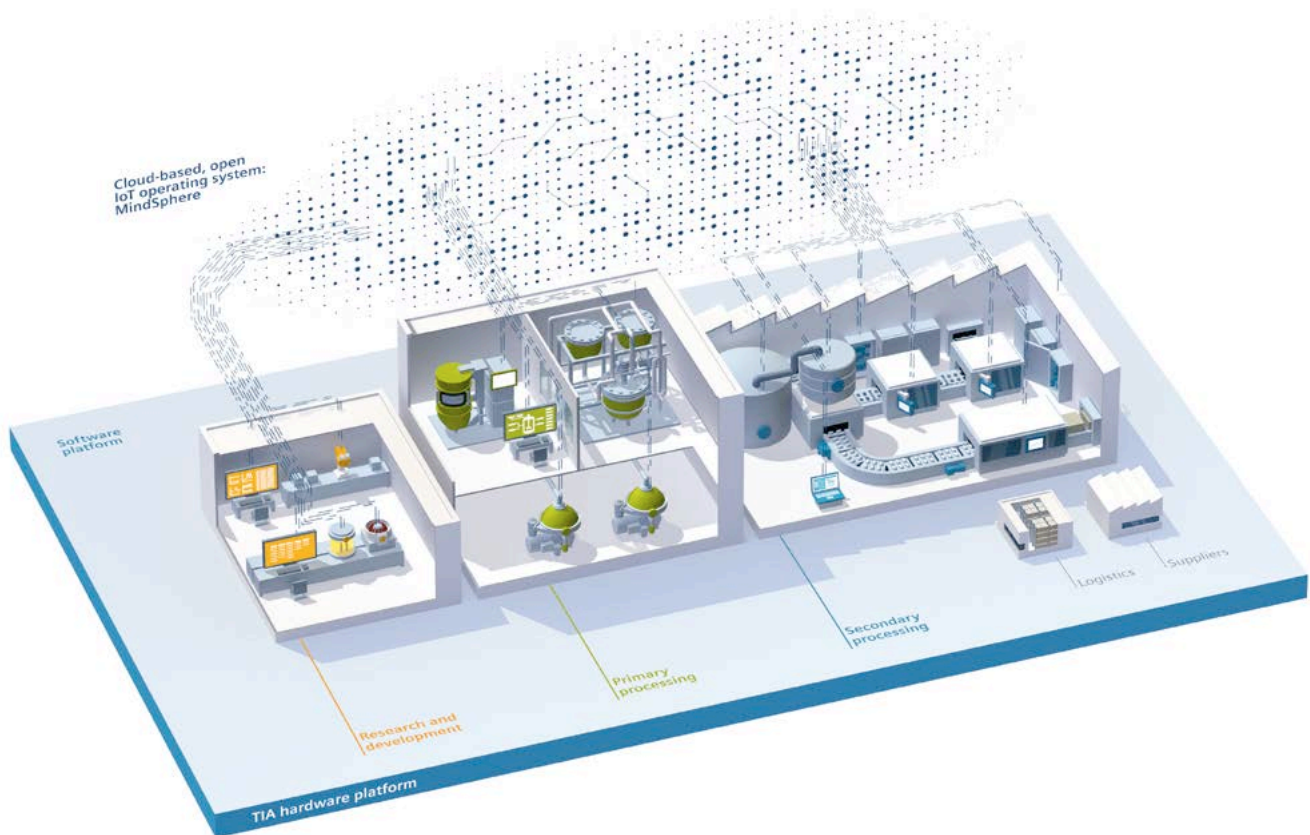


# The digital future in the pharmaceutical industry starts now



## Comprehensive approach

The pace of innovation and the ability to disrupt are becoming key success factors in global competition. As a lifecycle partner of the pharmaceutical industry, we offer our proven digital solutions and services.

Contact us and win the race for shorter time to market, right-first-time quality, and maximum production flexibility and efficiency.

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

Siemens AG  
Process Industries and Drives  
Pharmaceutical Industry  
Germany

Subject to change without prior notice  
Article No.: VRPH-B10013-00-7600  
Dispo 41513  
WS 08182.0

Printed in Germany

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**SIEMENS**

*Ingenuity for life*



# Win the race against time

Proven digital solutions for  
the pharmaceutical industry

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

# Win the race against time

## **Proven digital solutions take you to the next level**

In the pharmaceutical industry, quality is essential – cutting-edge research, excellent processes, and perfect products are what makes you the leader. Nevertheless, you need to improve to stay ahead: new diseases require new cures and increased competition requires faster, leaner processes in all aspects of your operations.

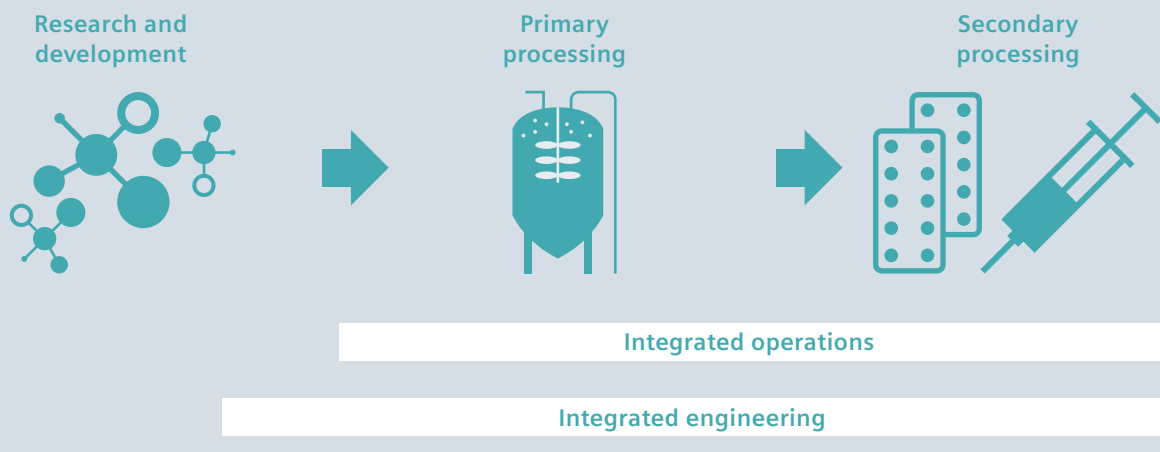
## **Taking the fast lane to integrated operations**

To address the challenges of future R&D and production requirements, the pharmaceutical industry needs solutions that enable operations to become more flexible and productive. Digitalization can help cut time to market, and further improve quality by supporting right-first-time production through data integrity and consistency across the value chain.

## **Solutions and services for the entire value chain**

Research and development, primary processing, secondary processing – every stage of the processes used in the pharmaceutical industry has its own specific demands. Being fully compliant with the latest regulations and guidelines is as important as is transforming the entire value chain into an integrated product and production lifecycle. We support you with our comprehensive portfolio of digital solutions and services for products, systems, and applications. This way you can work in compliance with Good Manufacturing Practice (GMP) and win the race against time.

## Product and production lifecycle



## Drivers for digital transformation



### Reducing time to market

- From idea to production
- Continuous manufacturing
- Flexible and modular standards



### Ensuring quality and compliance

- Right-first-time production
- Data integrity
- Data consistency



### Increasing flexibility

- Personalized medicine
- Data integrity from lab to patient
- Plug and produce



### Improving efficiency

- Operational excellence
- Resource efficiency
- Global collaboration



## Research and development

# Set the pace for innovation

Discovering new drugs can take years, and it can take even longer to bring a new treatment to patients. Now is the time to focus on improving your efficiency in research and development processes.

Streamline your drug research and development processes. No more laborious tracking of lab tests and results, no more trial and error approaches to recipe and process design, no more time-consuming compilation of data for records and documentation.

Utilize the latest digital solutions to enable a seamless transition of lab data and recipes to production by integrating R&D with process and product development. With our solutions for R&D, you will transfer new products faster from the lab to clinical trials to market and set the pace for innovation.

## Personalized medicine



### Personalized medicine is the future

One of the keys to future medical care lies in flexible and needs-based production. However, the development of personalized therapies presents major challenges – not just scientifically, but also in terms of production costs and time. By using our digitalization solutions, our customers are able to produce and release small batches efficiently and economically.

### Paperless manufacturing paves the way

SIMATIC IT eBR and Preactor enable the retrieval of all necessary information from the production processes. The system analyzes, archives, and compiles production records. This integration enables personnel to be deployed in an optimal way. Process steps can be executed correctly, and releases can be issued as and when required. You can execute even the smallest batches safely and efficiently with maximum flexibility.

## Living labs



### Digitalizing production processes

In our Living Lab in Vienna, we work on innovative solutions, especially for in-process quality control and verification to enable right-first-time processes. By replacing large-scale bioreactors with modular, small-scale fermenters, we have created a highly flexible production concept that can handle the growing complexity and diversity of bio processes. Integrated sensor systems, advanced process control technology, and powerful data acquisition and analysis tools foster process understanding. This enables continuous process optimization as well as the fast transition of new products to production.

### Real-time control for right-first-time

By connecting our SIMATIC PCS 7 process control system with SIMATIC SIPAT, we can support process analytical technology (PAT). The SIPAT software supports advanced data modeling and analysis for in-process monitoring of critical parameters. State-of-the-art simulation tools such as SIMIT enable fast and smooth deployment of process and product modifications. By integrating all these solutions, we demonstrate in the Living Lab how to design, develop, and test novel production concepts for bio processes.

## R&D suite



### Speeding up process and product design

The pharmaceutical industry has always been subject to stringent monitoring and regulations. However, in recent years the pressure from authorities as well as a shift in market requirements has changed the way new drugs are being developed and produced. Parallel development of drugs and processes can help shorten the time to market, as larger amounts of APIs can be made earlier. The experience gained from the small-scale process can be more easily scaled up or numbered up. Thanks to improved collaboration, you can better meet commercial production requirements.

### Seamless R&D and recipe data transition

With SIMATIC IT R&D Suite, we help integrate the various sources of data from preclinical testing to clinical trials and industrialization. You will benefit from structure and flexibility, enabling fast and successful drug development and time to market. This also includes lab automation, formula and process development, as well as specification and regulatory management.

## Primary processing

# Fast-track solutions

Manufacturing active pharmaceutical ingredients (APIs) requires complex processes that must comply with stringent system and product quality requirements, vital safety considerations, and a demanding regulatory environment. Manufacturing is being transformed from large-scale chemical APIs to individualized products, using single-use equipment to continuous manufacturing. Primary processing is as complex as it is diverse. At the same time, there is an ever-growing pressure to improve production efficiencies and throughput times.

With advanced digital solutions, you can handle all production challenges safely and efficiently, in full compliance with guidelines, and with complete process and quality transparency to help you optimize your production strategies and process performance. Our advanced digital solutions help you reap the benefits of improved process transparency and understanding.

## Integrated engineering



### Accelerating time to market

Digitalization is a vital instrument in picking up speed during a crucial phase of your value chain: the transfer of a new drug from R&D to production. With our solutions for integrated engineering and operation, you can streamline process development and maturity, and increase production flexibility and asset utilization at the same time – by ensuring data consistency across the entire lifecycle.

### Efficient engineering and management of pharmaceutical plants

Using COMOS, we offer a comprehensive software solution for the optimal integration of engineering and operation. Using a global, single data platform ensures consistent documentation and highly efficient plant operation starting from the planning stage. By combining with SIMIT and SIMATIC PCS 7, the automation level is extended, providing a central data management environment for plant engineers and operators. Your benefit: reduced time to market at lower costs.



## Paperless manufacturing



### Faster batch management and documentation

Our proven electronic batch record solution enables completely paperless manufacturing within regulated processes. It supports operational and manufacturing efficiency in both manual and highly automated environments – from the design of the batch record to the release of the batch report.

### Efficient electronic batch record management

With SIMATIC IT eBR, we offer a proven software solution for electronic batch record management that expedites the design, execution, review, and release of master batch records (MBR) and electronic batch records (eBR). SIMATIC IT eBR connects seamlessly with SIMATIC Batch. It electronically compiles critical data, and integrates manual and automated operations. This way, SIMATIC IT eBR enables review by exception. The results are faster information exchange and retrieval, and fewer human errors.

## Smart biomanufacturing



### Making biopharma processes smart

The race for smart biopharma processes is driven by three trends: personalized drugs, often tailored to the genome of the patient, as a new treatment option for both rare and widespread diseases; flexibility as a means to make plants smarter and adaptable; and finally using digitalization to acquire a deep level of process understanding. To improve yield, reduce time to market, and facilitate process validation, smart biological processes must deliver insights into biological behavior as well as process and product quality. Digitalization enables a deep process understanding for continuous, real-time quality control.

### Creating insights for smarter processes

Data-driven processes can make bio API production not only smarter, but more agile and reliable. We provide flexible automation systems that are easy to integrate and set up. This way you can win the race for smarter biopharmaceutical production.

## Integrated secondary lines



### Reduce your time to market

Our comprehensive approach integrates and optimizes the entire secondary manufacturing process. This way, you can reduce costs and processing times during the manufacture of solids and liquids. We support transparent, flexible processes and help you implement state-of-the-art manufacturing technologies.

The main factors driving efficiency improvements in secondary processing are making all processing units work together. From preparation to formulation to finishing to packaging, many different types of processes need to be smoothly coordinated, and products and data must be transferred safely and reliably.

With our solutions, you can eliminate lag times and costly procedures, and implement quality by design concepts in your lines. This paves the way for continuous manufacturing and optimally operating flexible and modular manufacturing units.

## Manufacturing of the future



### Explore the potential of digitalization

Digitalization is a game changer. The pharmaceutical industry can exploit this potential by utilizing state-of-the-art systems and technologies, and through networking automation technology, manufacturing execution systems, analytics, and information technology.

### Creating the factory of the future

In a pharmaceutical manufacturing facility, systems can be exploited to help manage operations, target operational efficiency, improve quality and compliance in the plant, and develop reliable and robust manufacturing processes for a new product. Our proven digital solutions for integrating data and context along the product lifecycle are based on COMOS, XHQ, SIMATIC IT and SIMATIC PCS 7. You will be able to improve the design phase to drive innovation and build confidence in experiments as well as make informed decisions based on data almost in real time. On the manufacturing floor, you can understand a process for related products faster, or even develop sophisticated models for specific products.

## Continuous manufacturing



### Win the race for higher productivity

Fewer deviations in production, higher yields, shorter time to market, and more profitable processes: With our solutions for continuous manufacturing, you can pave the way to higher productivity. Continuous production literally makes classic batch processes look outdated. The utilization of assets increases by 30% to 40%, and a product that previously took one or even two months in production is finished within two days.

### Outpace competition with right-first-time production

Release products faster and achieve continuous improvements through a data-driven process that is fully compliant with regulations and guidelines. The technological basis for continuous manufacturing is the use of process analytical technology (PAT). With PAT, you can determine the clinical efficacy of an active ingredient online by acquiring quality data directly in the process. SIMATIC SIPAT is one of the industry's most cutting-edge PAT tools. It enables pharmaceutical manufacturers to increase system utilization by a third and to lower their production costs by 10% to 20% after only a short time.

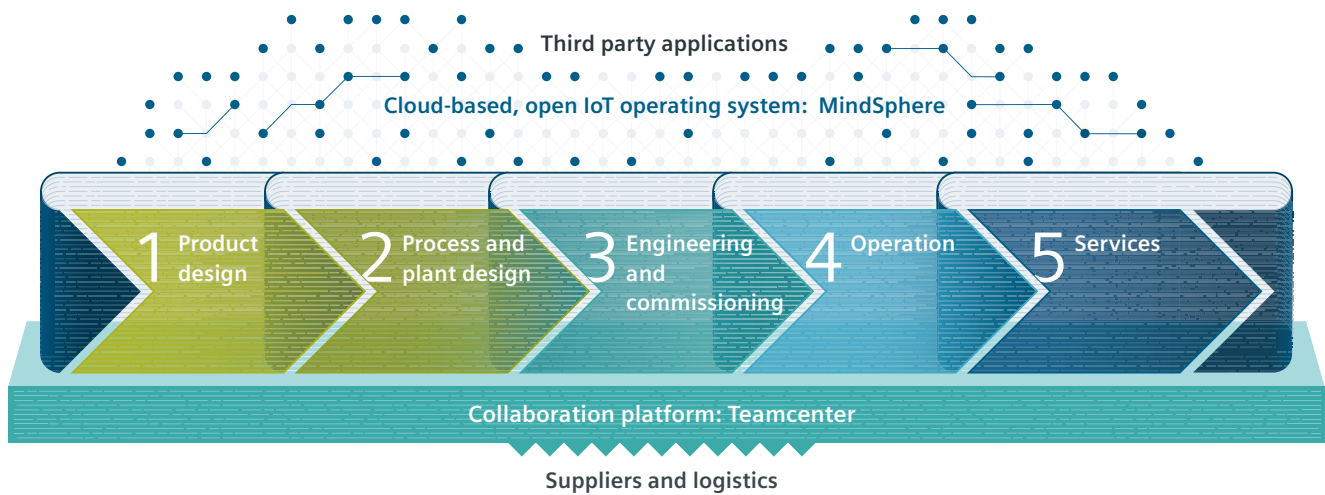
## Secondary processing

# Speeding up time to market

One of the keys to state-of-the-art secondary processing in the pharmaceutical industry is flexibility. That's why new drugs, personalized formulations, and new dosage forms drive the need for processing equipment that delivers the desired quality and output with minimum downtimes and versatile production options. Modular plants and production lines that can be individually combined for a given product are one answer to this.

Another is continuous manufacturing, which helps reduce lead times while reducing equipment footprint. It is necessary to successfully manage the growing complexity of lines and systems, meet the requirements for quality inspection and documentation, and also speed up the release of finished products.

# Digitalization through the value chain



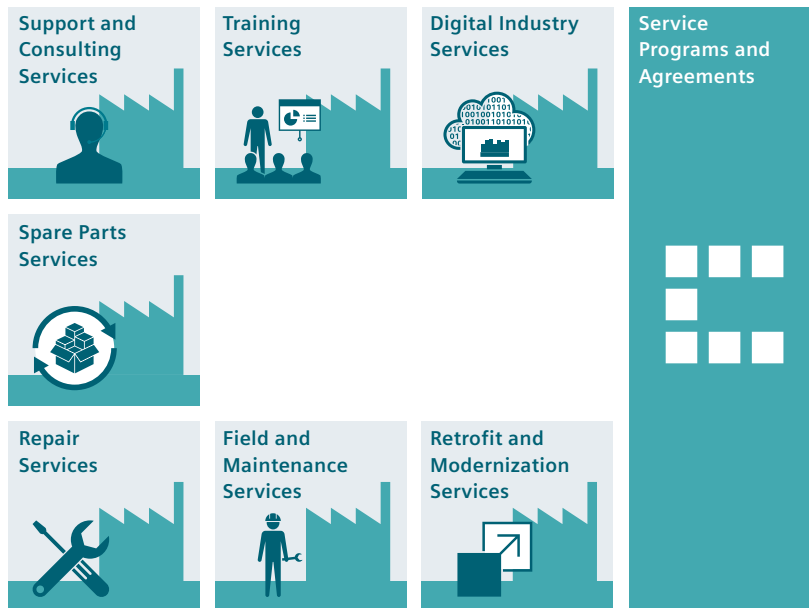
## Horizontal digitalization

Data integration along the lifecycle ensures an accurate, current, and consistent transfer of information from research and development to primary and secondary processing. This integrated engineering approach to life-cycle data helps you reduce the time from product development to market, optimize your production processes and capabilities, and aids you in maintenance and modernization by providing a common data model for analysis and simulation.

## Vertical digitalization

Vertical integration links the different levels during operations from the field and the automation level up to the management level. It helps you convert process and product data into meaningful information to support decisions and enhance productivity. Vertical digitalization will increase the level of process understanding and acts as a key enabler for continuous and smart production strategies that deliver maximum process flexibility.

# Add value with services



## A lifecycle approach to servicing your business

Minimizing downtime, optimizing personnel deployment, optimum use of assets and resources, and developing new digital business models: While we are focused on helping you achieve operational excellence in the shortest time possible, we know that performance, quality, and flexibility must also be ensured over the long run. Our experts will help you maintain, foster, and improve your operations in every aspect of your plant and process lifecycle: from support and consulting to training, from commissioning to spare parts to repairs, and up to maintenance, retrofit, and modernization. This is complemented by a unique portfolio of Digital Industry Services.

## A fast start with the right services for digitalization

Digitalization will make a huge impact on your business, on your team, and on your systems and processes. In order to choose the best digitalization strategy and to make sure you benefit most from the potential of digitalization, we support you with a tailored set of consulting services:

- **Digitalization maturity assessments**  
Together, we will identify your digitalization needs, challenges, and pain points and create a digital index along your value chain.
- **Digitalization workshops**  
Our digitalization workshop will help you understand the challenges along the value chain in more detail and provide you with workflows and timelines for digitalization.
- **Digitalization consulting**  
Together, we will define suitable project KPIs and the optimum implementation road map, including budget, ROI, technical specifications, and a detailed digital transformation plan.



# Outpace threats with industrial security



## Industrial Security helps protect your productivity

The risk of cyberattacks is growing along with digitalization and the increased networking of machines and industrial plants. With our proven solutions for Industrial Security, you can take the appropriate protective measures to keep your operations safe from harm. Our “defense in depth” approach to comprehensive protection offers defense throughout all levels and in accordance with the recommendations of ISA99 / IEC 62443 – the leading standard for security in industrial applications.

Sounds complex? We support you with a coordinated portfolio of solutions especially for the security of industrial facilities – from planning to implementation and monitoring.

## Industrial Security Services: specific concepts for reliable protection

Benefit from the comprehensive know-how as well as the technical expertise of our global network of specialists for automation and cyber security. Our experts support you in implementing an Industrial Security solution that is perfectly aligned with your operations and needs. We analyze your status and requirements, assess strategies and systems, and help you deploy the identified measures, from configuring a firewall to training plant personnel.

Siemens’ IT experts also have a deep knowledge of automation systems so they are fully qualified to manage the security of your production facility.