

... grow

**Increase your productivity:**  
Pharmaceutical solutions with substance

Flexibility will ...

Industry  
Suite

# pharma

**SIEMENS**



know-how



# know

# Know-how

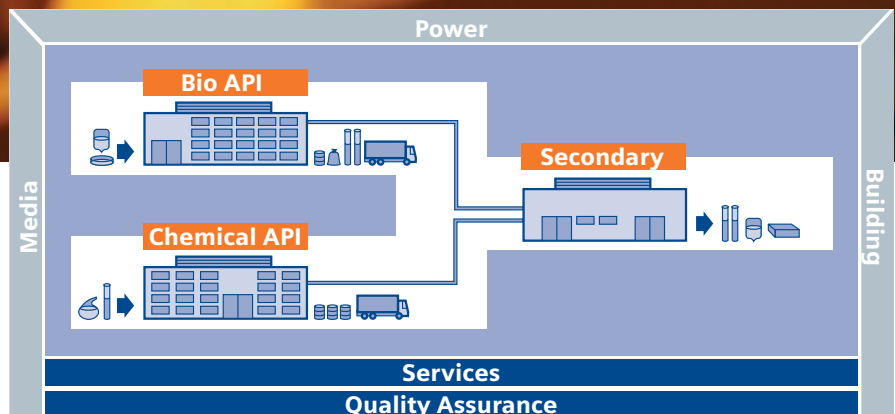


## Understanding **business needs**

Requirements in the pharmaceutical industry are more diverse than ever. This makes it all the more important to have a partner with process know-how who not only knows the specific requirements of process engineering and equipment building, but also has a sound understanding of your processes and regulatory requirements. Thanks to our long years of experience, our continuous dialog with your sector, and our process and automation competence, we provide you with comprehensive support over the entire process; implementing solutions that help provide sustained optimization of your processes.



know-how





*Increased productivity, more flexibility, complete process transparency, guaranteed and controlled quality, integrated validation, more effective manufacturing methods, and minimal time-to-market – the challenges in the pharmaceutical industry are becoming more and more complex.*

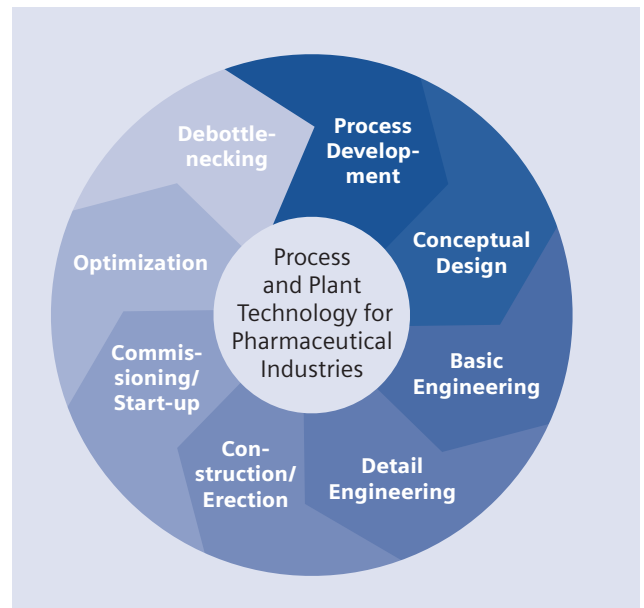


## New active ingredients for more productivity

Whether you're talking process engineering, process development, plant or equipment building – it is your experience and needs that have been channeled into our products and systems for years. We are responding to your requirements for improved production efficiency and shorter time-to-market by converting them into concrete solutions. We have taken decisive steps forward on this road and are currently bundling our industry know-how with our competence in the areas of automation, power engineering, and service solutions to form the **Pharmaceutical Industry Suite**.

With these unique capabilities, we are able to offer you a solution portfolio which fits your requirements. A portfolio that takes a holistic view of all four substages of the production process – incoming goods logistics, primary process, secondary process, and logistics for outgoing goods. Making it possible to generate cross-boundary solutions that boost your productivity, maximize your value across the entire life cycle, and increase your competitiveness on a lasting basis.

We will use all our experience and know-how to help you optimize and implement solutions that fit your needs.



### **Bio API/Chem API – from the raw materials to the finished active ingredient**

On the way to the finished active ingredient, a lot of regulations have to be met, along with the highest safety and product quality requirements. With our know-how in this complex environment, we provide you with integral support – from process design and development, through engineering and automation, right up to operation. For a shorter time-to-market, improved product exploitation, and more efficient use of existing resources.

### **Secondary process – controlling process quality**

No matter what products you manufacture, constant product quality with maximum economic efficiency and safety is always the clear priority. With our solutions, we open up new potential for you for controlling and documenting the process as a whole – with all its lower-level phases such

as planning, formulation, filling/pressing, and packaging; always conditional on making your production process as flexible as possible.

### **Utilities – optimal conditions for optimal processes**

Optimizing environmental and utility services plays a crucial role in good product quality. This affects, for example, building automation, energy, and supply of water, steam, high-purity air, and other utilities with optimal interfaces for production planning and process automation. Requirements you can meet with Siemens.

### **Laboratories – increasing efficiency**

Safety for employees, products, and data, more efficient sequences, increased flexibility, and optimal utilization of space are the core requirements for labs. Thanks to flexible architecture, all our solution components can be seamlessly integrated into your building automation system, and beyond this they are open for future expansions.

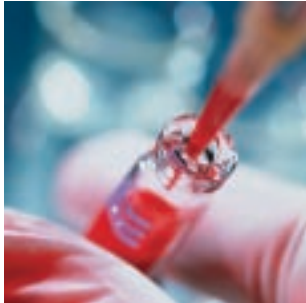


**know-how**



### **Validation**

Pharmaceutical companies are facing increasing pressure to ensure compliance with the applicable regulatory requirements. Being a major challenge for the life science industry, validation should be carried out at a reasonable cost in cooperation with a competent, reliable, and qualified partner. Siemens supports its customers in order to meet the requirements for GMP-regulated plants by offering comprehensive support for validation during the entire drug life cycle. Incorporating the validation-related activities from the early beginning, considerable amount of time can be saved to obtain a successfully validated system. Amongst others, validation services as retrospective validation, compliance and risk assessments, plant qualification, clean-room qualification, and GMP-consulting are within Siemens' service portfolio.



### **FDA 21 CFR Part 11**

The pharmaceutical industry is becoming more and more dependent on information technologies. Via the 21 CFR Part 11 rule, the FDA has defined the regulatory requirements that must be met for FDA acceptance of electronic records and/or electronic signatures.

Siemens takes into account the 21 CFR Part 11 regulatory requirements for the development and application of the products in their portfolio. As additional services, Siemens can assist in performing 21 CFR Part 11 risk and compliance assessments of existing systems, including the set-up of remediation plans.

## Offering **comprehensive solutions**

With our Pharmaceutical Industry Suite, we offer you a unique, optimally matched range of products, systems, hardware, software, services and process know-how with which you can best meet present and future challenges. We provide comprehensive support over the entire life cycle of your plants, equipped with the know-how that counts in your sector, and the relevant resources to give you sound advice quickly concerning all your process needs. Whether you're talking overall solution, partial solution, or individual package – you decide what we can do for your success. One thing is always clear: with our Industry Suite, specific plant solutions can be developed faster and more easily, and they can be expanded more simply and more flexibly than ever before.

solutions

# solutions

### **Modularization, standardization, and integration**

Our Pharmaceutical Industry Suite is based on our standard products. Thanks to our open platforms, Totally Integrated Automation and Totally Integrated Power – the core of the Industry Suite – can be configured, used, and combined system-wide without significant overhead for your sector.

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## Benefits for the Pharmaceutical Industry

- Higher productivity
- Shorter time-to-market
- Improved quality in production
- Higher availability of the plants
- Better asset management of plants or entire production networks
- Transparency and brand protection in the production and distribution process

### Process know-how:

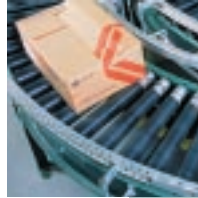
#### Understanding technological requirements

With the integration of Siemens Axiva into the Siemens network, we offer you competence, in process engineering and automation engineering, unique in the industry. We support you by quickly providing first batches and sample batches, and we help you achieve a significantly shorter time-to-market. Along with synthesis, process development, scale-up, and small batch production, our know-how also encompasses wide-ranging consulting services, for example, in selecting, assessing, and using technology, or support in matters of economic efficiency.



### Logistics Automation: Products, Systems and Solutions

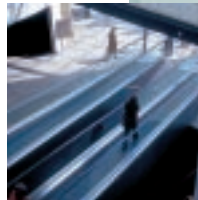
As the worldwide leading supplier, we can offer you an integrated modular system where all components that are relevant for the perfect functioning of an automated logistics solution come from a single source. This includes mechatronics as well as IT and the innovative system solutions developed from them. A fundamental aspect of our philosophy is the Life Cycle Concept, which comprises integrated solutions – from consulting, planning and implementing a project right up to coordinated service offers for the life cycle performance of a plant.



### Energy concepts:

#### Tailor-made power supply for processing plants in the pharmaceutical industry

From incoming supply to the consumer, from energy management to emergency power supply – with our modular NXAir and NXAirPlus switchgear, we can design and implement reliable, fault-tolerant power supplies exactly to your needs. Our comprehensive know-how guarantees secure, stable, and economical compliance with all process-related requirements. And we offer you solutions with maximum flexibility for expansion or production changes, selective protection of your supply systems, and seamless integration in management and control systems. For optimum efficiency and productivity over the entire life cycle of your plant.



### Building automation: For a first-class production climate

We offer you specific solutions and technologies for building automation – from high-tech clean room conditions to the office environment. With many years of experience and excellent know-how, we ensure building management systems that comply fully with validation requirements, and enable an optimum low level of energy, maintenance, and operating costs.

## Industry Suite

### Totally Integrated Automation

#### Innovations for increased productivity

With Totally Integrated Automation, we offer you an automation platform for process and manufacturing automation, including Safety Integrated, that is still unique in the world. Just like the information flow, all the partial steps in production can be integrated system-wide, from the field level right up to the corporate management level. This promises more cost-effective engineering and efficiency as well as increased profitability across all processes.

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### MES solutions:

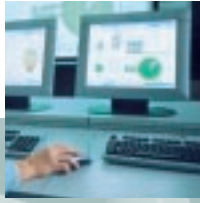
#### Manufacturing optimization – horizontal and vertical

In the area of MES, we provide you with a wide range of products for optimizing your operations. Our component approach with SIMATIC IT Framework and the modular SIMATIC IT Components is unique in the world.

Your solution can be implemented quickly on the basis of standardized products and pharmaceutical

### IT solution providing: Transparency at all levels

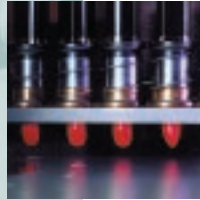
For optimized production processes, it is important to have relevant information available at the right time and in the right place. Our solutions for IT integration support you in creating transparent information flow, coordinating individual machine functions, identifying production and logistics data, controlling sequences, or linking corporate management with the production level. Highly developed enterprise resource planning and supply chain management systems optimize the entire workflow, even beyond plant and company boundaries.



### Machine solutions:

#### Starting up with the machine faster and at lower cost

For many years now, we have been setting standards in machine and equipment building and actively driven innovation; always with the intention of reducing your costs of ownership. Innovative products such as the SIMOTION motion control system that guarantees simpler engineering, easier integration, improved quality, higher safety, and shorter downtimes. Modular machine concepts allow you to respond quickly to changed market situations, and can be integrated optimally into distributed automation solutions; or SINAMICS, our new integrated drives family, enables modular and scalable drives solutions across the entire performance bandwidth that can be flexibly adapted to individual tasks and easily expanded.



## Totally Integrated Power

### Power distribution and management from a single source

With Totally Integrated Power, we offer you integrated solutions for power distribution in utility buildings and industrial buildings, from medium voltage to the outlet. Equipped with the same communication and visualization standards as Totally Integrated Automation, all the resources for automation, power distribution, power management, and building automation can be integrated, and cross-boundary solutions for your sector can be implemented.



### Life cycle services:

#### Services for the entire life cycle

Siemens offers you services in every project phase of your plant, from design, through engineering, operation, and maintenance, right up to retrofit. Resulting in optimized solutions for improved and more profitable processes. Our comprehensive service portfolio provides a range of offerings including the service and support for your plants to reduce life cycle costs, individual service tasks, complete maintenance contracts, and operations of your facility.



### System integration: Our partners near you

Our cooperation with Solution Partners and System Integrators provides you with a widespread network of process specialists and automation professionals in your local area. Around the world, the quality seal of the Siemens Solution Provider has long been established on the global market as a badge of world-class services.

specific modules. This makes it easier to optimize operations control linked to the business processes and to modify production processes, thus reducing life-cycle costs.

Our systems for identification and brand protection ensure greater transparency in the production and distribution process. In this way, you can obtain long-term synergetic benefits between production and distribution and thus reliably protect the future of your brands.

/pharma



reliability

# reliability

# mbility



## **Totally Integrated Automation –** A reliable foundation, capable of expansion

Today more than ever before, it is necessary to consider the workflow as a whole in all parts of the company and to link up production processes and commercial and planning procedures as closely as possible. For all three dimensions – vertical integration, the life cycle process and the supply chain – we can offer you an all-inclusive system platform: **Totally Integrated Automation**. This system enables concepts that are considerably more productive for mechanical engineering and plant construction. It also ensures maximum productivity on all levels of your company aside from the actual automation aspect. And what's more, it grows as technology changes and, thanks to its stability, safeguards your investment over the long term.



## Totally Integrated Automation Update

### SIMOTION

The all-round, modular and scalable motion control system for complex motion control.

### SINAMICS

The new, all-round and complete drive generation for all performance, design and voltage classes.

### PROFinet

The new standard for industrial Ethernet communication.

### MOBY

Identification systems support transparency and brand protection in the production and distribution process.

### Component-based Automation

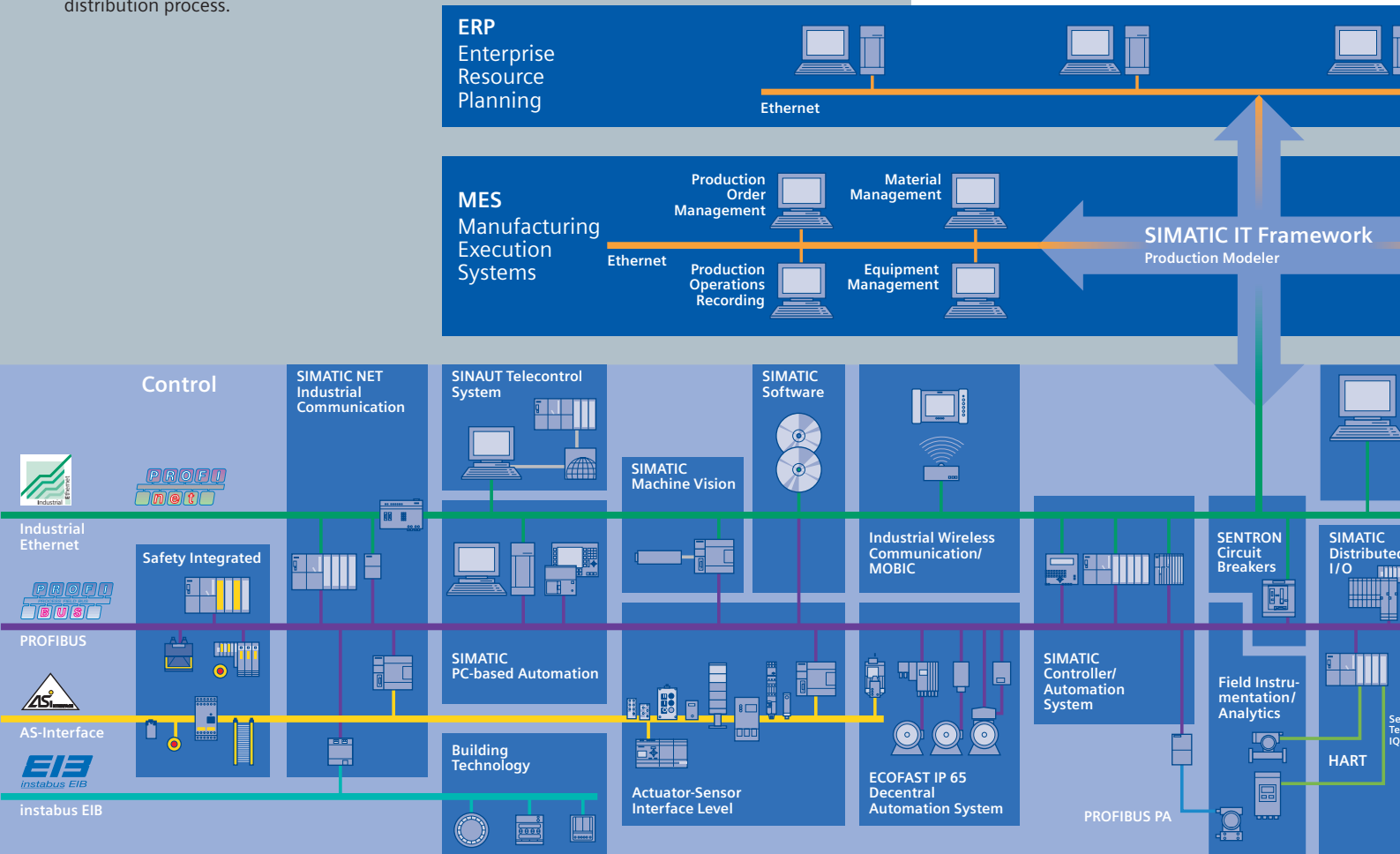
Simple-to-replace machine or equipment modules ensure shorter start-up and conversion times.

### Safety Integrated

The integrated safety technology via PROFIBUS and AS-Interface.

### ECOFAST

The integrated, standardized connecting system for communication and power distribution with a high degree of protection.





## This is Totally Integrated Automation: Integrated software tools ...

From the planning phase to intelligent maintenance strategies during ongoing operation, you can use integrated software tools that make use of a shared database. This ensures that your data remains consistent at all times.

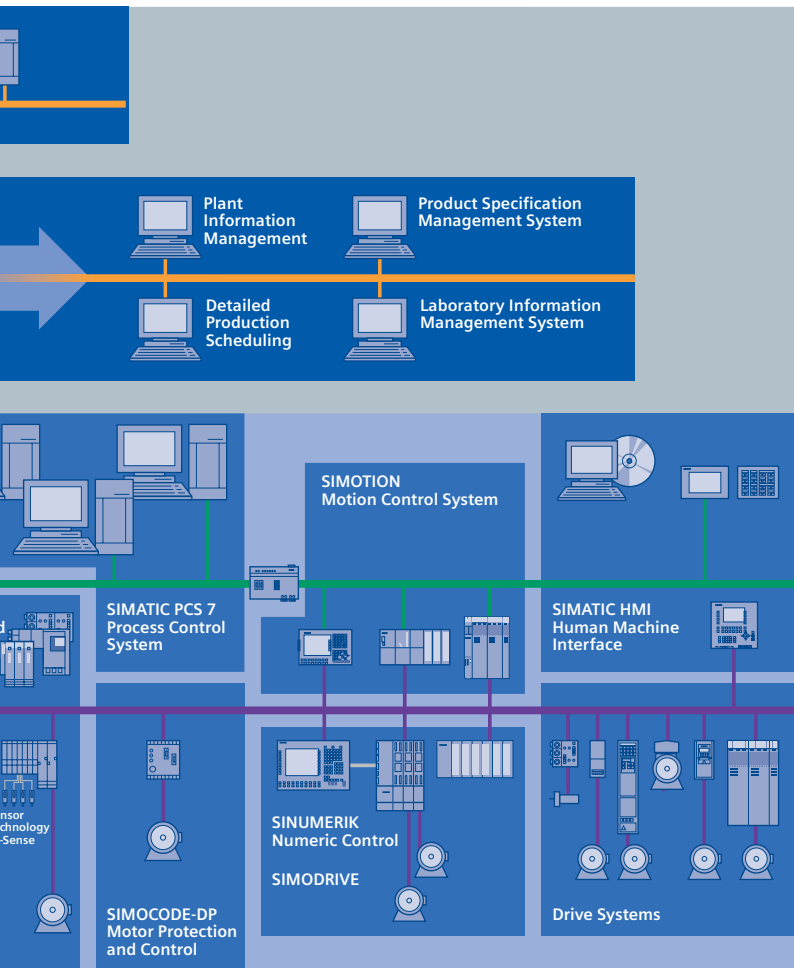
## ... and uniform communication mechanisms

All hardware and software components incorporate a variety of communication functions. Connections, even via different networks and between different platforms, are extremely easy to configure. Communication thus reaches all the way, from the subordinate field level to the corporate control level. It is based on internationally recognized standards and uses Internet technology to support the worldwide flow of information.



## ... across the whole spectrum

Totally Integrated Automation covers the whole spectrum of tried-and-tested, innovative automation and drive systems – from the field level to SIMATIC controllers, from PC-based automation, HMI systems, identification systems, support of brand protection to SCADA and SIMATIC PCS 7 process control systems. With the help of SIMATIC IT, it also links the automation to the corporate control level. Minimum engineering overhead and maximum productivity. That is what we mean by Totally Integrated Automation.



# Interested in our "active ingredient"?

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