PROCESS INSTRUMENTATION & ANALYTICS

Maintain a hygienic environment and uniform product quality with Siemens devices.

Designed to meet the strictest industry standards

usa.siemens.com/pharma

SIEMENS

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Your challenge is our passion

Pharmaceutical manufacturers are seeking to press ahead quickly in response to competitive and pricing pressures in the pharmaceutical market. Improvements in performance and capability are high on the agenda with the goals of reducing time-to-market, lowering the cost-base, increasing quality and efficiency and matching market requirements with a demand-driven supply chain. At the same time, regulatory changes provide significant opportunities for improvement and innovation in the production and manufacture of pharmaceuticals.

The competitive environment for pharmaceutical manufacturing is more intensive than ever. Wider scientific and demographic trends are also shaping the future direction of production. We are not far from a time when pharmaceutical manufacturing will need to prepare for an era of personalized medicines. At the same time, the patient population is living longer with a consequent impact on demand and the creation of additional pricing pressures. Pharmaceutical production is preparing for a future that will see new flexible manufacturing strategies being deployed alongside high-volume output.

Gaining control of processes and integrating them with overall manufacturing control systems and demand-driven logistics chains will be the key to future success. Siemens delivers world-class capabilities to meet the challenges faced by pharmaceutical manufacturers. Siemens is able to address a number of vital process instrumentation and analytics requirements. Its global reach and product portfolio enables Siemens to meet your development needs and requirements.

When you partner with Siemens, you get:

- A product portfolio for key process steps in the value chain
- Solutions to improve productivity, quality and supply challenges
- Fewer different components – simplifying spare parts inventory and ensuring highly efficient maintenance
- The assurance of a leading global brand delivering leading-edge automation technology
- People who understand your industry needs and can configure solutions to match your operating conditions

Your partner **for precision**

Precision and accuracy are vital in pharmaceutical manufacturing. Patient safety and regulatory compliance are critical. Companies need to enjoy complete trust and confidence, knowing that their process instrumentation allows them full control over their operations.

Whatever part of the industry you focus on, whether you are a manufacturer of biological or chemical active pharmaceutical ingredients (APIs) or are engaged in dosage vector manufacturing, you can be assured that Siemens quality and product know-how will help you meet your business and customer goals:

Product life cycle planning
You need a partner who can meet your needs throughout the entire life cycle of your product, whether by hastening the drug from trials into full-scale market production or by helping you to achieve manufacturing excellence and while maintaining a competitive cost-base.

Optimal asset valuation
The diagnostic capabilities of our instrumentation solutions, in combination with evaluation and MES systems, provide you with the information you need to leverage maximum productivity from your manufacturing assets. You are able to plan effectively for any production changes and maintenance.

Pharma knowledge
Our products and knowledge of the industry can help you stay at the forefront of the pharmaceutical industry with respect to regulatory compliance and your competitive edge. We appreciate, for example, that process analytical technology (PAT) is much more than just sensing and includes both design and production. Similarly, we offer extensive experience of compliance with the requirements of 21 CFR Part 11.

The Siemens approach:
- Emphasis on user-friendly products – for safer operation
- High degree of product safety – through maximum process transparency
- Optimal resource efficiency – through innovative platform concepts
- Flexibility – for faster and safer manufacturing changeover
- Increased productivity – with optimal solutions for the operating phase

Customer benefits:
- Fast commissioning, short ramp-up times
- Low total cost of ownership (TCO)
- Quick return on investment
- Continual improvement through innovative service and support concepts
- Traceability to ensure manufacturing quality through completely integrated production
- Maximum compatibility and innovation assuring your confidence in the future

Level

Flow

Pressure

Temperature

Positioning

Weighing

Process protection

Gas analytics

CGA

In-situ

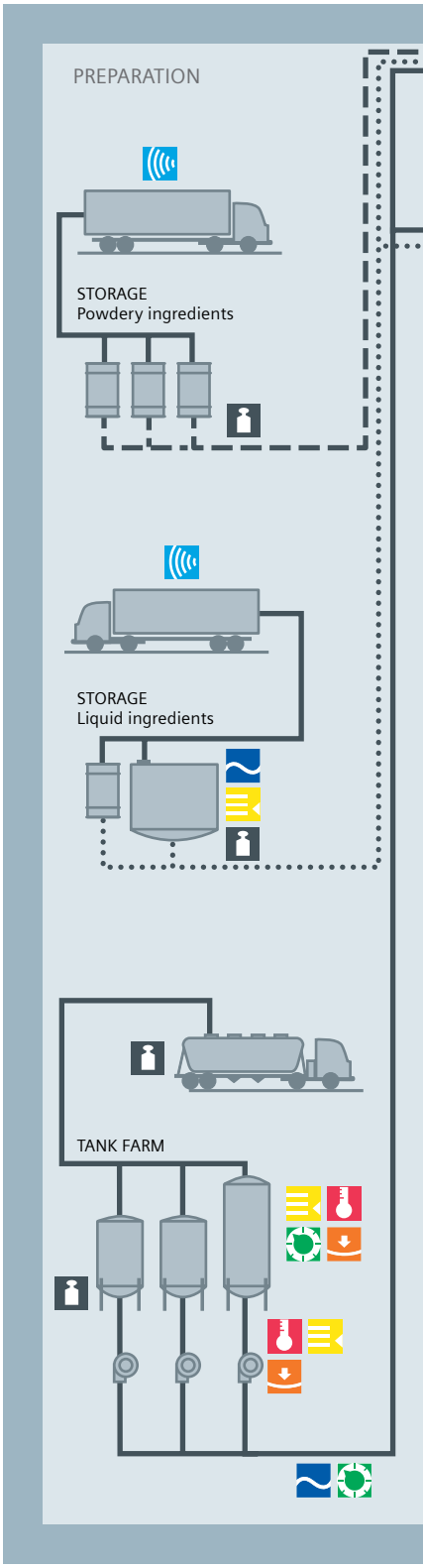
Identification

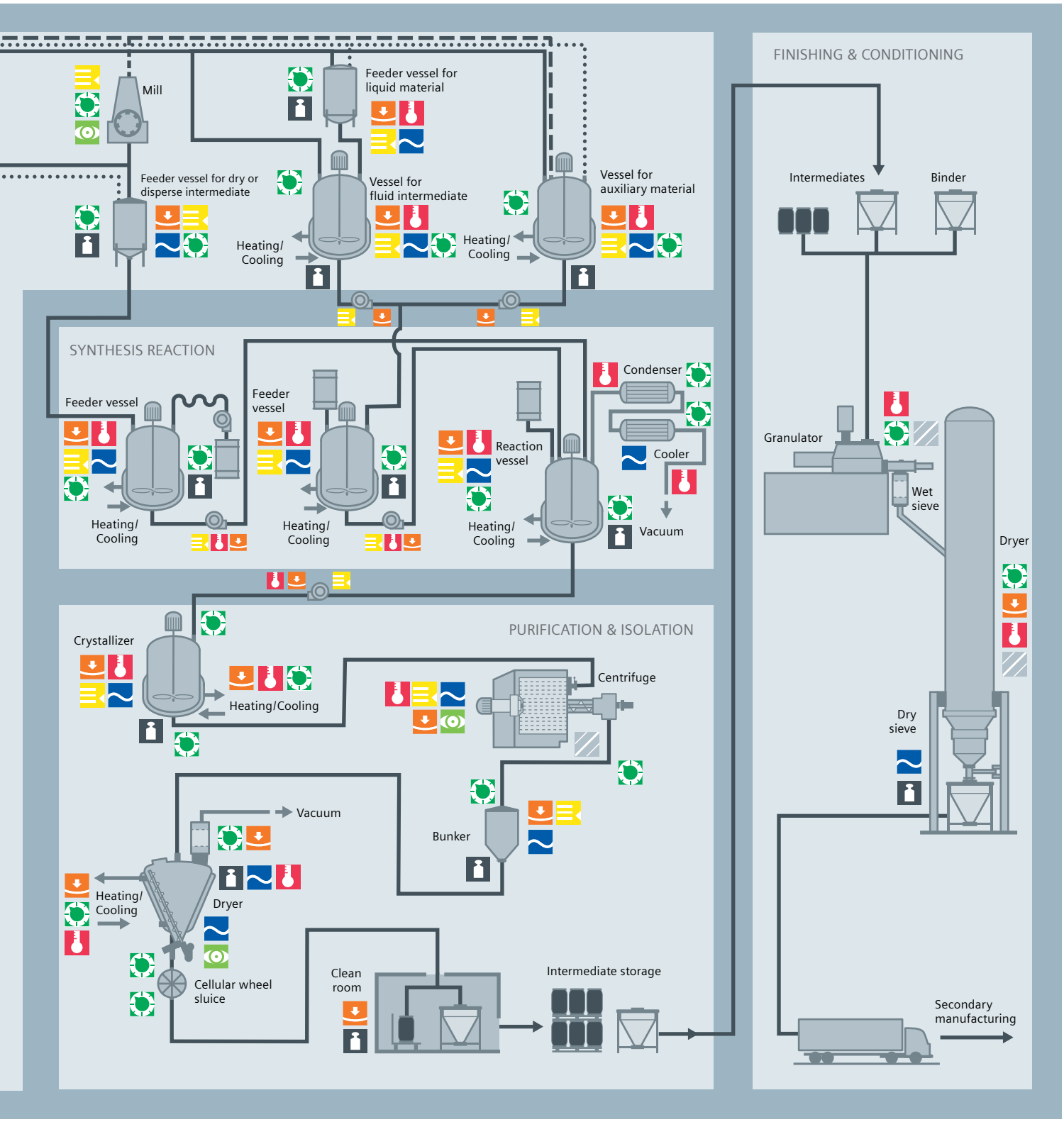
Software

Chemical Active Pharmaceutical **Ingredients (Chem APIs)**

Companies that manufacture Chem APIs operate to very high quality and safety standards. The handling of complex chemical reactions in hazardous areas is routine work in this particular sector. Safety is a priority – for employees and with respect to product safety.

The observance of efficient protection measures is essential when handling highly active pharmaceutical ingredients. Staff must be protected from the product while the product must be protected from contamination. A high degree of plant flexibility is often required to facilitate the successive manufacture of several Chem APIs in a batching system. This requires efficient and reliable measurements, which not only fulfill hygienic requirements, but also guarantee secure handling in hazardous areas.





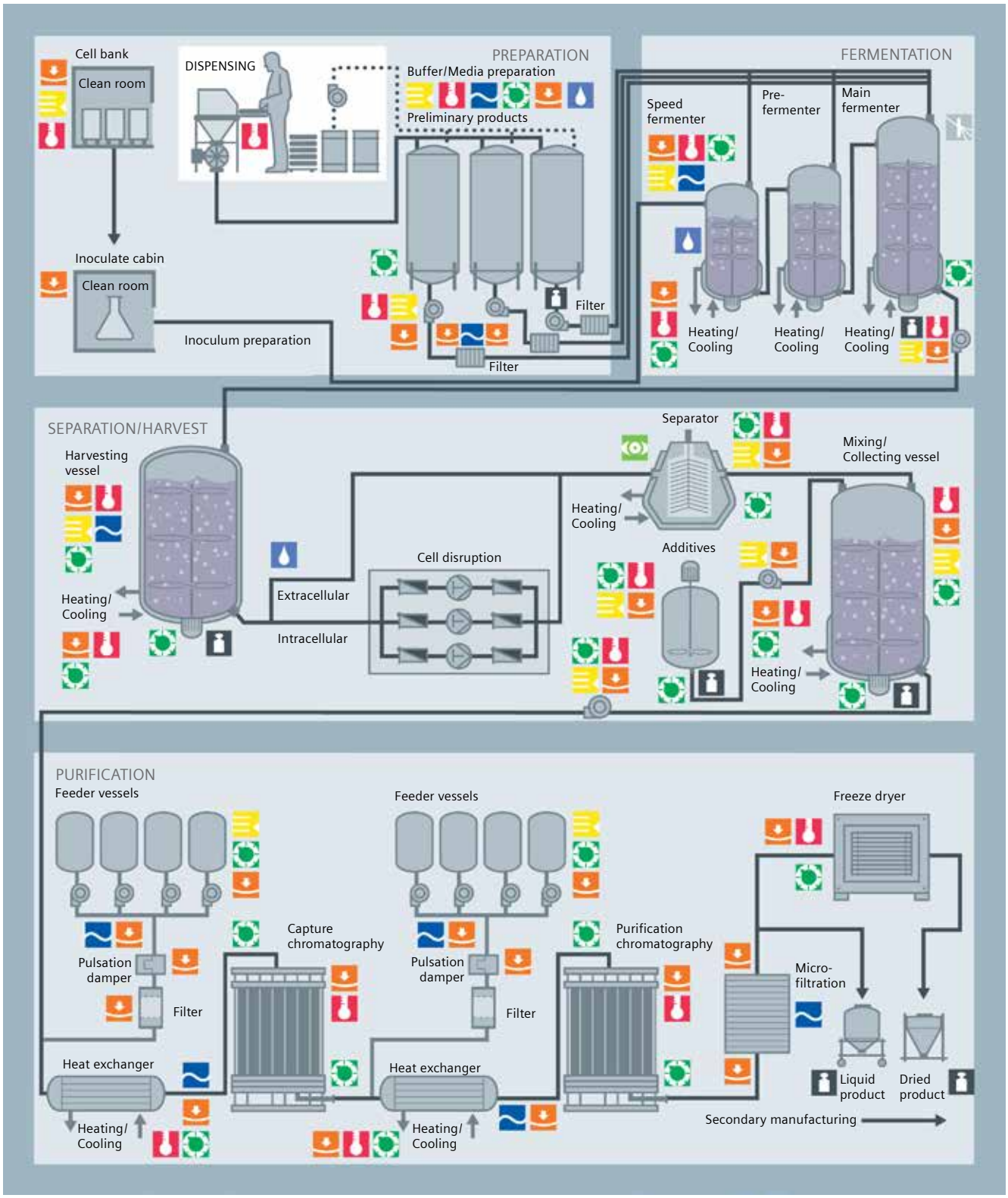
Level Flow Pressure Temperature Positioning

Process protection CGA Identification Weighing

Biological Active Pharmaceutical **Ingredients (Bio APIs)**

Much of the future of the pharmaceutical industry belongs to biotechnologically manufactured active ingredients. As a rule, Bio APIs are very expensive products with high temperature and shearing sensitivity. They are also sensitive to pH, pressure, contaminants and the accumulation of waster material, all of which requires a complex concentration and separation process. Fermentation lies at the heart of the production process for these substances. The challenge is to create the right grouping of conducive materials, buffers and air/gases that facilitate the optimum environment for the growth and production of cultures.

The product is harvested and cleaned after fermentation, rendering it usable as a Bio API at a later stage. The procedure demands high requirements on hygiene and reproducibility. The subsequent downstream process, wherein the desired molecules are separated and purified, also poses considerable challenges. The requisite investment in plants and equipment is considerable. Precise control and measurement of the fermentation and downstream processes is essential in securing increased reproducibility and uniform consistency.



Level Flow Pressure Temperature Positioning

Process protection NIR Weighing

Pharmaceutical **manufacturing (solids)**

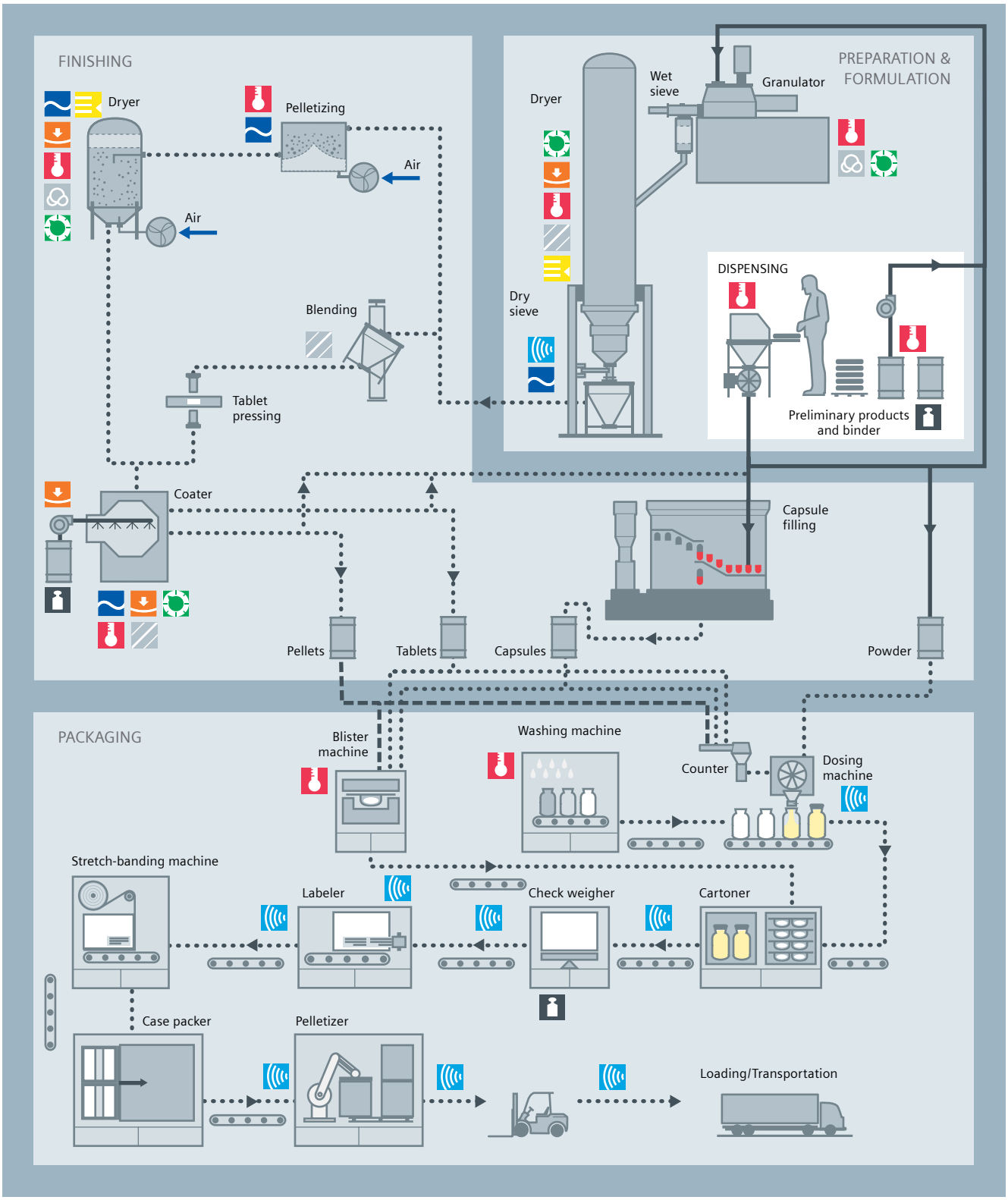
Active Pharmaceutical Ingredients (APIs) must be formulated in such a way that the patient receives the prescribed dosage. Products are manufactured in a variety of different vectors: tablets, capsules, solutions, suspensions, emulsions, gels, creams (oil-in-water emulsions), ointments (water-in-oil emulsions) and aerosols (containing inhalants or substances suitable for topical use).

Maintaining high quality standards under increasing cost pressures characterizes drug manufacturing today. A central aspect of the design of new process pharmaceutical manufacturing plants and the upgrading of existing ones (in addition to the equipment) is the creation of sanitary zones and installation of concomitant HVAC systems. Many production logistics variables, including the flow of materials and personnel, must also be taken into account.

Projects in drug manufacturing often require the expeditious integration of complex technologies in an existing production center. To eliminate manufacturing downtimes as much as possible, implementation and assembly typically need to take place during ongoing operations. The successful deployment of such projects requires careful planning, excellent industry experience and reliable products.

Solids

Stand-alone production units characterize the manufacture of solid dosage forms. Each unit operates in accordance with pharmaceutical-specific and technical methodologies that are monitored constantly by means of multiple sensors. All processes must be coordinated in order to maintain optimum flow and meet production safety stipulations.


FINISHING
Dryer
Pelletizing
Air
Air
Blending
Tablet pressing
Coater
PREPARATION & FORMULATION
Dryer
Wet sieve
Granulator
Dry sieve
DISPENSING
Preliminary products and binder
Capsule filling
Pellets
Tablets
Capsules
Powder
PACKAGING
Blister machine
Washing machine
Counter
Dosing machine
Stretch-banding machine
Labeler
Check weigher
Cartoner
Case packer
Pelletizer
Loading/Transportation
Level
Flow
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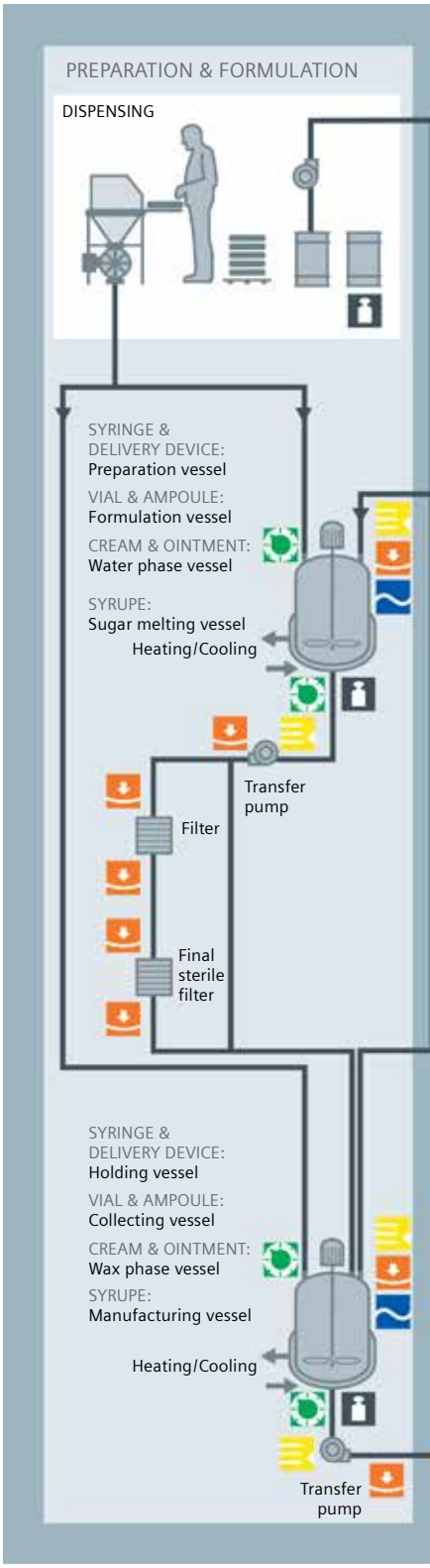
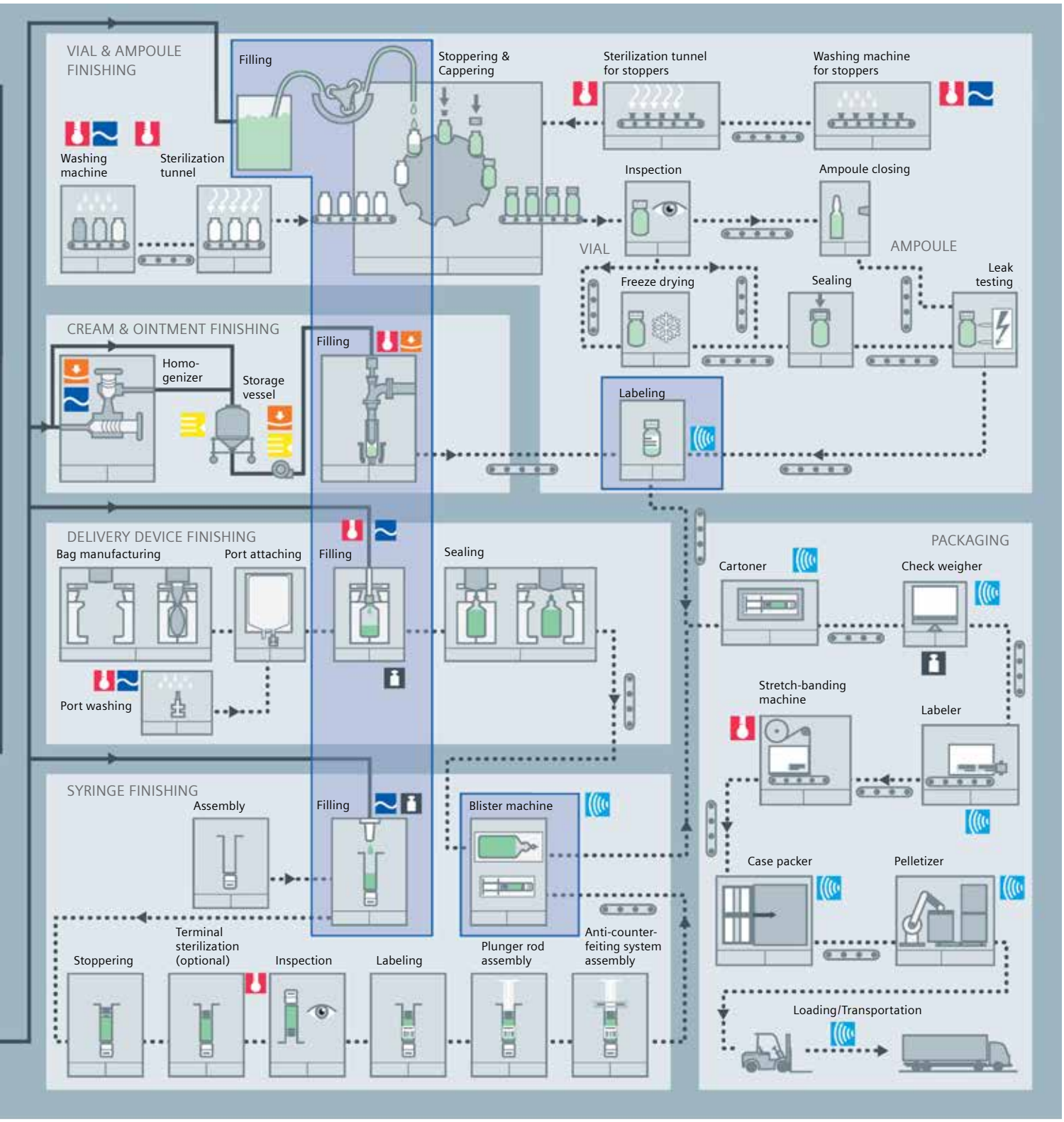
Positioning
Gas analytics
CGA
Identification
Weighing

Pharmaceutical **manufacturing (liquids)**

Liquids

Liquid mixing and liquid blending are two of the most complicated pharmaceutical manufacturing unit operations. The blending of dissimilar fluids, such as oil and water, or the incorporation of solids into the liquid manufacturing process makes liquid mixing and liquid blending a processing challenge. Siemens equipment, underpinned by technical knowledge, provides exact monitoring of your process, thus ensuring consistent product quality.





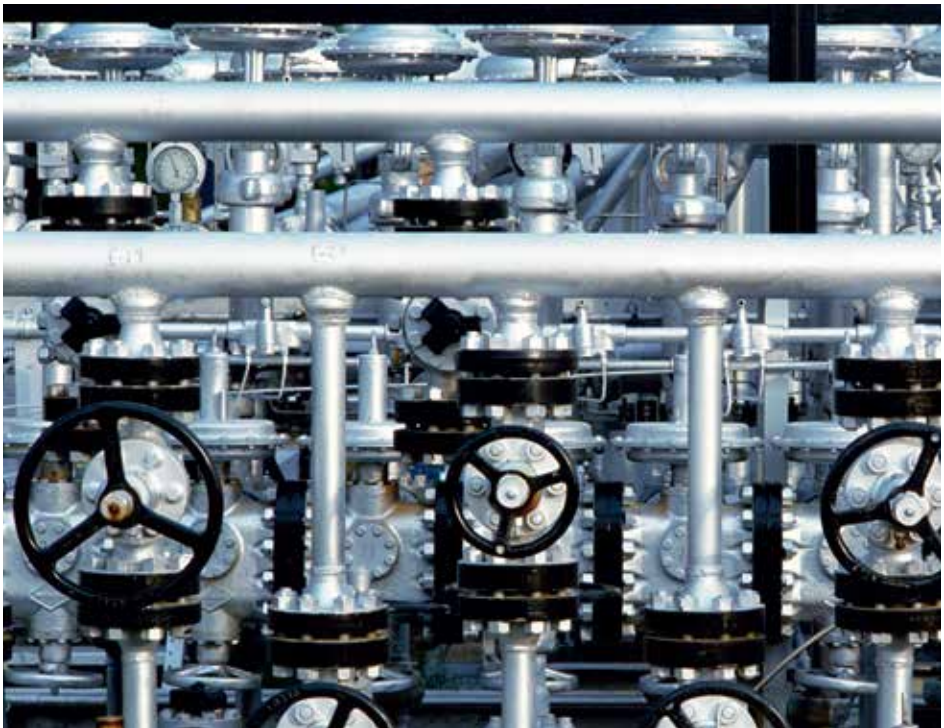
Level Flow Pressure Temperature Valve positioning

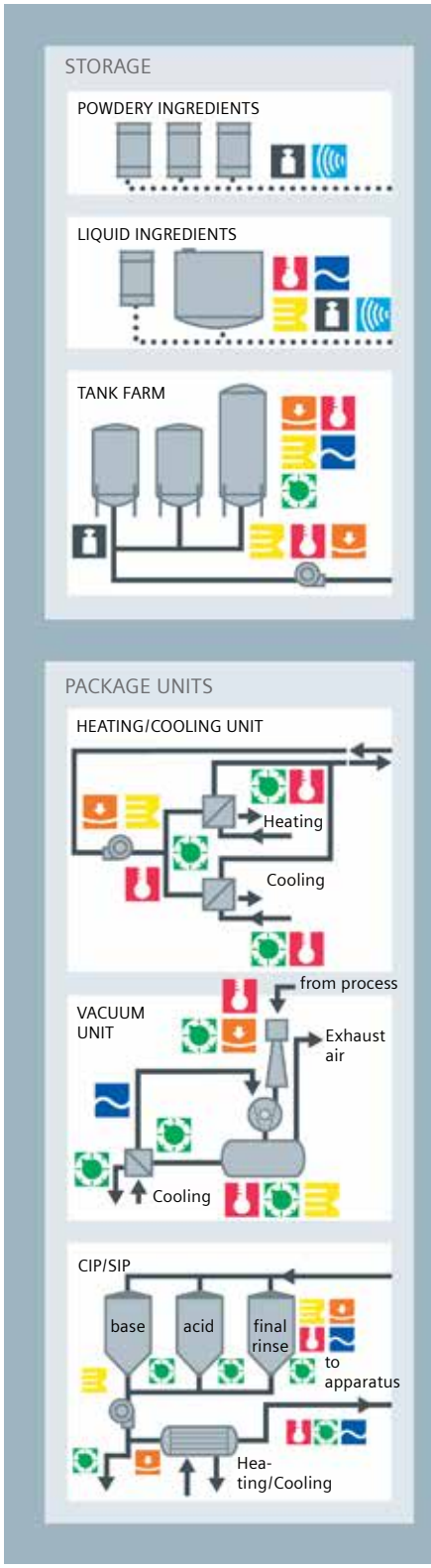
Weighing Identification

Infrastructure

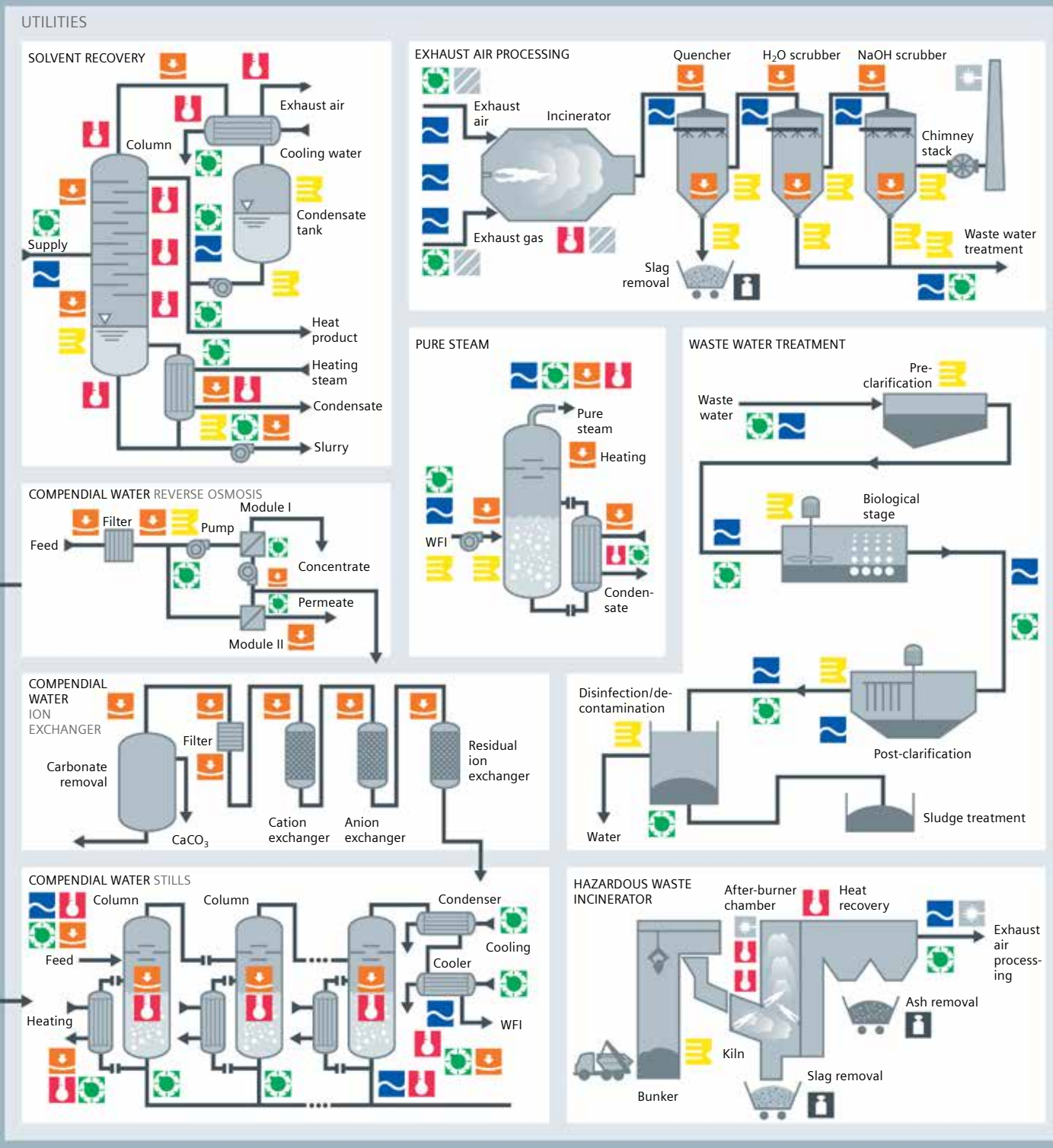
Utilities are indispensable to efficient pharmaceutical manufacturing. Their impact on the cost-effectiveness of a production site is immense. A reliable supply of purified water, water for injection, and pure steam must be guaranteed at all times during operation, and at a consistently high quality. Such quality is also a prerequisite within the distribution network, twenty-four hours a day. Intelligent concepts and measurements play a vital part in the reliable delivery of this important resource.

At the end of the production process, wastewater and flue gases are generated, especially in the manufacture of APIs. Emissions can be minimized in production but may not be entirely avoidable. Therefore, the remaining off-gases and effluent outflows must be treated safely and cost-effectively in order to meet allowable discharge limits while maintaining the availability of the entire manufacturing site and ensuring environmental protection.





UTILITIES



Level Flow Pressure Temperature Valve positioning Weighing

CGA In-situ Identification

Pressure

Precise measurement combined with hygienic design make the SITRANS P300 ideal for applications in the pharmaceutical industry. The precision of the device enables manufacturers to optimize efficiency and increase plant productivity. The stainless steel housing and front flush diaphragm guarantee a dead space-free measurement and offer easy cleaning.

SITRANS P300 pressure transmitter

The P300 is built to withstand temperatures of up to 150 °C (302 °F). It can also be used with a temperature decoupler in situations where even higher temperatures (up to 250 °C / 482 °F) are encountered. Unlike the decoupler, it does not affect accuracy. Reliability is thus assured even in very hot conditions.

The SITRANS P300 offers drift-free usage over a very long period even where continuous sanitization is in place, providing the pharmaceutical industry with a new dimension. The construction and design of this transmitter is in accordance with the rules and standards of EHEDG (European Hygienic Engineering and Design Group) and 3 A (Sanitary Standards, Inc.).

- SITRANS P300 highlights
- A digital pressure transmitter offering 'three push-button' handling and extensive diagnostics as well as simulation functions
- The stainless steel housing and measuring cell is designed according to hygienic requirements
- Suitable for CIP and SIP processes
- A broad range of communication options (HART®, PROFIBUS PA, FOUNDATION Fieldbus) combine with SIMATIC PDM to ensure easy and seamless integration in the world of SIMATIC
- Exact and stable measurements over a long period, e. g. a reference accuracy of < 0.075 % with a long-term stability up to 0.125 % in five years

Temperature

Siemens offers many differently designed resistance thermometers and thermocouples to the pharmaceutical industry. All these sensors are equipped with the process connection systems required in the pharmaceutical industry and are designed in accordance with hygiene requirements. Construction and materials meet FDA, EHEDG and 3 A standards.

SITRANS T resistance thermometers

Siemens temperature sensors can be installed as clamp-ons (measuring temperature without media contact). These clamp-on resistance thermometers can be easily retrofitted without interfering with operations. Because it is clamped on, the device does not intrude in the process in any way or disrupt the flow. The temperature sensor with pipe collar can be used for temperature monitoring, particularly for sterile applications. Temperature measurement is possible following simple, fast assembly on any existing pipeline system. It is not necessary to interrupt the pipeline or to carry out welding. Assembly on the pipeline is simply implemented by adapting the two halves of the collar. The device can also be supplied with an integral transmitter as an option.

- Resistance thermometer highlights
- Temperature measurement free of dead space
- Can be retrofitted onto existing pipelines
- Matches all common nominal pipe diameters
- Optimum temperature measurement using metallic pressing system
- Insulating collar made of temperature-resistant plastic, easy to clean
- Measuring range –20 to +200 °C (–4 to +392 °F)
- Replaceable Pt 100 measuring insert; thus no changes in measuring setup
- Calibration possible
- Transmitter can be integrated (4 to 20 mA, HART®, FOUNDATION Fieldbus or PROFIBUS PA)

Valve positioning

Nearly all pharmaceutical processes in primary production are deployed by means of controlled valves. Next to many other additional features the SIPART PS2 provides precise valve monitoring and diagnostics of events in case of error.

SIPART PS2 valve positioner

Next to advantages like an easy installation and quick commissioning the SIPART PS 2 is equipped with comprehensive functionalities, and delivers diagnostic data on itself, its environment and the valve and actuator. With these premium diagnostics, this positioner sets the standards for cost efficiency, reduces maintenance requirements in the plant, guarantees safe process control, and provides high functional safety in emergency situation. The diagnostics package that is included in every device as standard without additional costs includes functions for pneumatic leaks, valve wear, static friction, stiffness and much more. Additionally, the SIPART PS 2 ensures with a regular partial stroke test that ESD (emergency shutdown) valves and other open/close automated valves remain movable in the event of an emergency.

All diagnostic features at a glance:

- Alarm status based on NAMUR NE107
- Partial stroke test for open/close and control valves
- Pneumatic leaks
- Stiffness of a valve
- Stiction of the packing
- Wear of, deposits or caking on the valve seat or plug
- Failure of the valve or actuator shaft
- Trend diagrams, Histograms
- Stroke counter for fitting, Direction reversal counter, operating hours counter
- Deadband and temperature measurement

- SIPART PS2 highlights
- The No. 1 among smart electropneumatic positioners
- Standard Makrolon® enclosure to IP66/NEMA4x protection, with optional aluminium or stainless steel enclosure
- Versions with external non-contacting travel sensors
- High flexibility in the stroke range from 3 to 200 mm (0.1 to 7.9 inch) or more
- Communication via PROFIBUS PA, FOUNDATION Fieldbus or HART

Weighing

Weighing and proportioning is a central aspect of successful pharmaceutical production. Our high-quality and competitive weighing products offer users complete accuracy in the process and optimum productivity in the plant. In other words, absolute reliability and the highest production speed at the same time. With Siemens, you get competence and comprehensive expertise in both automation and weighing technology. Siemens has been a leader in both fields for many years – worldwide.

SIWAREX weighing technology

Batch, loss-in-weight, bagging and check weighers are only a part of the areas for state-of-the-art weighing technology. For all kinds of applications, SIWAREX offers a wide range of weighing electronics as well as load cells and corresponding mounting accessories. All components are suitable for usage in environments with highest requirements in hygiene.

The direct integration of SIWAREX into SIMATIC enables a continuous and open solution for the demands of weighing tasks within the automation structure.

Whether SIWAREX is used central in SIMATIC or local by using PROFIBUS or PROFINET, the integration stays continuous and flexible for expansions. Interface standards, integrated functions, standard tools and well-prepared 'ready-to-use' applications support a quick and cost-effective configuration.

- SIWAREX highlights
- Provision of all typically needed weighing modes
- Expandable by further weighing modules at any time
- Calibration, parameterization and operation via standard HMI or Windows tool
- Legal-for-trade approval
- Integration into control cabinet avoids contact with the product
- Load cells and mounting accessories in stainless steel
- Efficient communication and data handling due to cross-linking to PROFIBUS or PROFINET
- Diagnostics and maintenance possible via teleservice
- Accuracy of 0.1mg in combination with digital load cells

Software

With different communication protocols and the necessary software, Siemens offers the right tools to integrate its process instruments and analyzers into the world of process automation.

SIMATIC PDM (Process Device Manager)

SIMATIC PDM (Process Device Manager) is a cross-vendor tool for configuration, parameterization, commissioning and diagnostics of intelligent field devices based on international EDD standard (Electronic Device Description; IEC 6/804-2). It ensures seamless integration for the instrumentation and analytics that Siemens offer.

- The following core functions of SIMATIC PDM serve to control devices and processes utilized in
- process automation
- Setting and modifying of parameters
- Parameter plausibility check
- Archiving of parameter sets in a consistent database
- Documentation of parameter sets
- Comparison of parameter sets
- Calibration support
- Loop tests
- Online diagnostics
- Communication with process devices uses the HART® protocol, PROFIBUS or other protocols.

Process Instrumentation and Analytics product range

Siemens offers the most comprehensive product range for the pharmaceutical industry and has a solution for even the most difficult measurements.

Flow measurement

Electromagnetic flow meters

Siemens full series of flow meters for liquids and slurries gives a wide range of customer-specified process connections.

Coriolis flow meters

The SITRANS FCS100 is a highly versatile sensor thanks to its rigid construction and compact design, making it ideal for applications that require multiple sensors to fit into small spaces. Its plug-andplay interface simplify installation, while its rugged stainless steel enclosure protects against corrosion. The FSC100 low flow sensor is well suited for processes ranging from mini-plants in the pharmaceutical industry to harsh environments within the chemical and oil and gas industries.

Clamp-on ultrasonic flow meters

Ultrasonic clamp-on flow meters provide an accuracy of 0.5 to 1% of flow rate for liquid flow measurement. The external transducers can quickly and easily be installed on the outside of pipes ranging from 0.5" to 394" in size. There is no need to cut the pipe or stop the flow, maintenance is minimal.

Pressure measurement

SITRANS P

SITRANS P offers a complete range of instruments for measuring relative, differential and absolute pressure. The SITRANS P300 has a hygienic stainless steel housing with laser-etched nameplate. The SITRANS P300 meets the requirements of EHEDG, FDA and 3 A. Cleaning and sterilization are standard practice.

Temperature measurement

SITRANS T

The clamp-on thermometer offers quick and highly accurate measurement without disturbance of the process and provides easy recalibration. Equipped with our unique SITRANS TH or TR transmitters, we offer the turnkey solution. Classical wetted temperature sensors complete the temperature measurement portfolio.

Weighing

SIWAREX weighing systems

SIWAREX provides a comprehensive range of weighing electronics and load cells for hopper, platform, batching, bagging and belt scales as well as solids flow meters and loss-in-weight applications. Secure your investments with SIWAREX electronics featuring SIMATIC hardware and seamless integration into Step 7, TIA Portal, or PCS 7.

Level measurement

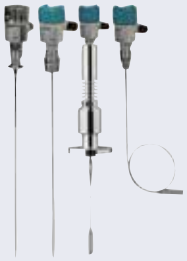
Radar

Liquids level measurement

SITRANS LR100 series are 80 GHz compact radar transmitters with Bluetooth wireless technology. Featuring a narrow beam for flexible installations in existing vessel openings – or non-intrusively through plastic vessels.

Solids level measurement

SITRANS LR500 series are 80 GHz radar level transmitters for continuous monitoring of liquids, slurries, and solids in storage and process vessels.



SITRANS LG 240/ 250/ 260/ 270

2-wire, guided wave radar transmitter for short- to medium-range level, level/interface, and volume measurement of liquids and solids for inventory and process control including hygienic applications.

Positioning

SIPART PS2

Positioner for linear and rotary actuators. Particularly flexible stroke range, intelligent diagnostics and communicates either via HART, PROFIBUS PA or Foundation Fieldbus.

Process Protection

Motion sensors

Siemens motion sensing probes for the SITRANS WM300 MFA can be mounted up to 4" from the ferrous target, reducing the chance of damage to the probe and the equipment. SITRANS WM100 zero speed alarm switch provides equipment protection even in harsh environments.

Acoustic monitoring

SITRANS AS100 detects changes in high-frequency sound waves resulting from particle impacts on equipment. In combination with SITRANS CU02 alarm control unit, it detects and reacts instantly to changes in solids flow.

Remote monitoring and displays

SITRANS RD100/150/200

SITRANS RD100/200 are remote displays for process instrumentation. The SITRANS RD150 is a remote digital display for 4 to 20 mA and HART devices.

Ultrasonic

SITRANS Probe LU240

SITRANS Probe LU240 ultrasonic level transmitter is a two wire, loop powered, cost-effective, compact, intelligent level solution for liquid inventory in all industries

SITRANS LT500

SITRANS LT500 MultiRanger/HydroRanger is the next evolution of digital level, flow, and pump controllers for radar and ultrasonic transmitters – or any 2-wire 4-20 mA device. It is the first choice for radar sensor measurements at 80 GHz and features single and dual point measurements, 6 relays, and Modbus RTU, HART, PROFIBUS DP, PROFIBUS PA, PROFINET.

Point level

Point level switches

Modern point level technology plays a number of critical roles in your operations – either as a backup technology or on its own. Backup alarming to material presence detection and/or point level monitoring, protection against running empty, or a cost-effective choice for material detection – Siemens' range of point level devices covers it all. Capacitance, rotating and vibrating level switches are suitable for virtually all applications from bulk solids to liquids, and everything in between.

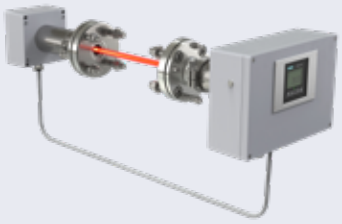
Process Analytics

Ultramat 23

The ULTRAMAT 23 is an innovative multi-component gas analyzer which can be equipped with the following sensors: IR detector for IR-active gases, UV photometer for UV-active gases, H2S sensor (electrochemical), O2 sensor (electrochemical or paramagnetic), and used accordingly in numerous applications and industries. The integrated automatic calibration function using ambient air provides the unique advantage of requiring a test with calibration gases only once a year.

Series 6

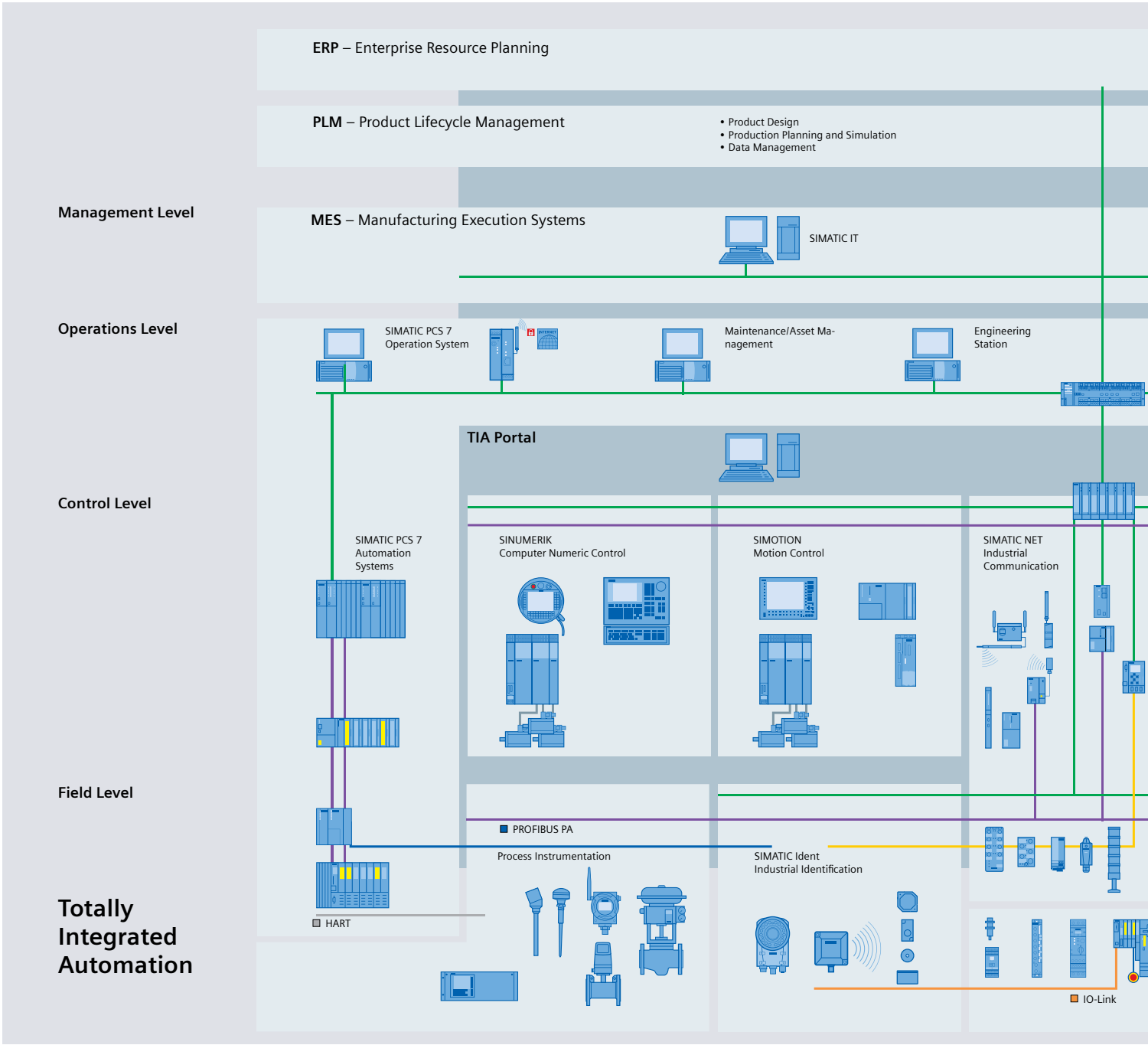
A practical combination of the ULTRAMAT 6 and OXYMAT 6 analyzers in a single enclosure. The ULTRAMAT channel measures CO, CO_2, NO, SO_2 and NH_3 as well as CH4 and other hydrocarbons. The OXYMAT channel measures the oxygen content of gas. Cleanable sample cells and optional corrosion-resistant materials in the gas path make measurement of highly corrosive sample gases possible.



SITRANS (TDL)

The SITRANS TDL gas analyzer consists of a pair of cross-duct sensors, an emitter unit and a receiver unit, containing all the needed hardware and algorithm to perform the actual measurement. The sensors are meant to be mounted directly on the process with no need of sampling systems, for a pure so called in situ principle. A laser beam at a specific wavelength is sent from the transmitter, passing through the process gas, absorbed by the targeted molecules, reaching the detector on the receiver side. The measurements are carried out online with an excellent response time.

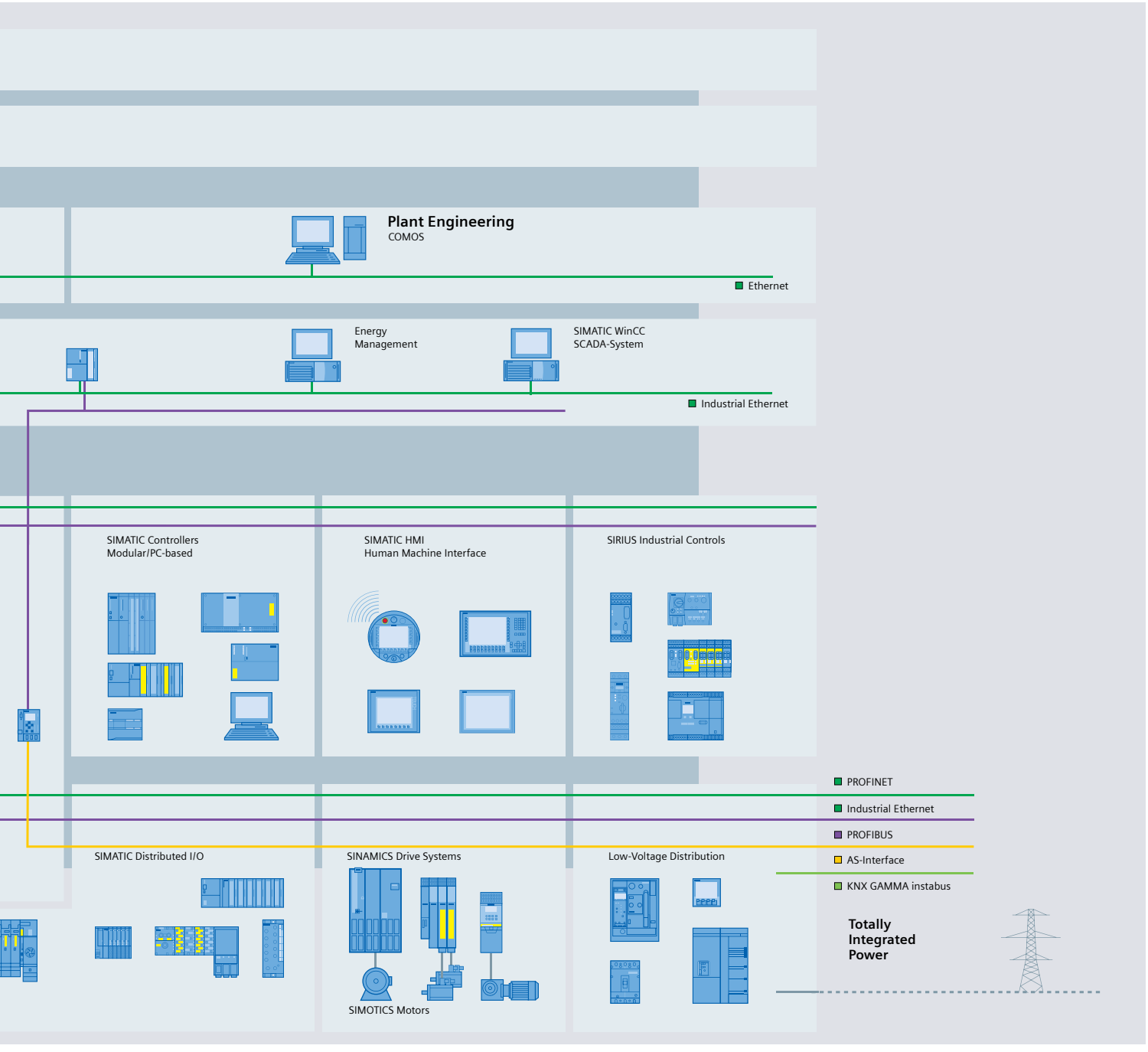
Totally Integrated Automation



Products from the controller level to the field level
With Totally Integrated Automation (TIA), Siemens is the only provider of an end-to-end integrated portfolio of products and systems for the automation of the entire production workflow. From the goods receiving area to the finished goods warehouse.

Totally Integrated Automation reduces the complexity of the automation solution and enables what really counts: the practical combination of optimally coordinated individual components – without interface problems.

Totally Integrated Automation integrates not only the production process but all parts of the company – from the field level to the management level. The result: a perfectly coordinated overall concept that enables higher productivity.



Example: SIMATIC PCS 7. The innovative process control system offers numerous options for connecting I/Os as well as for sending and receiving process signals via sensors and actuators.

Industrial Identification

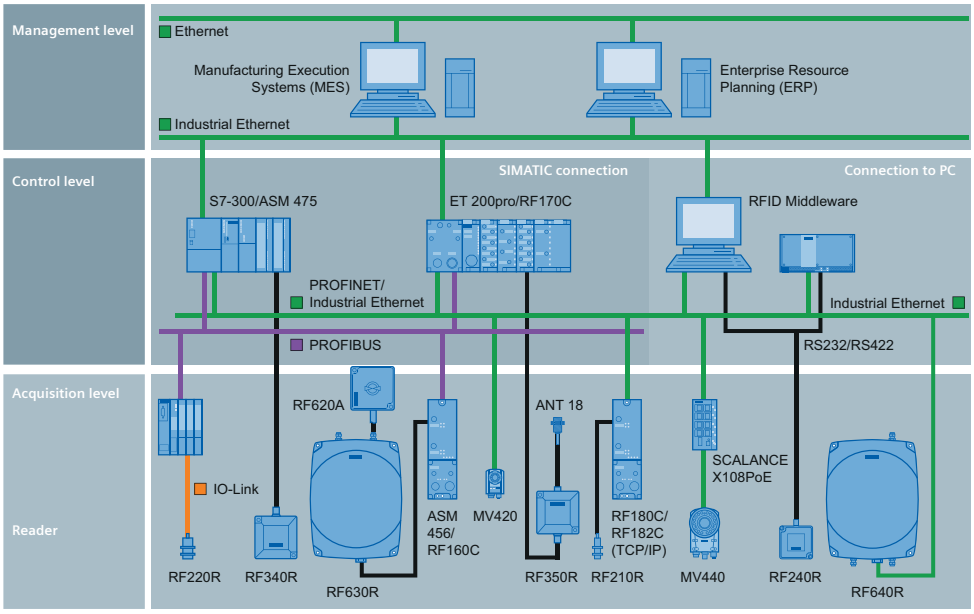
Today, efficient tracking and tracing plays an increasingly important role in all industries. Legal requirements and rising demands for process quality have made full traceability with the perfect identification system virtually indispensable. The best answer for addressing this challenge: SIMATIC Ident, our comprehensive industrial identification portfolio, which offers complete documented histories of products, components and systems. With industrial identification, each product leaves a digital trace that can be traced and documented all the way back through its individual component parts.

Industrial identification for sustainably efficient processes

Machine-readable, automated and contactless identification systems synchronize virtual data streams in the IT systems with the actual flow of goods and ensure maximum transparency – not only in production processes, but also in the external logistics processes. Advantages are created along the entire supply chain: quality requirements can be reliably met, production can be more flexibly structured, the number of manual operations reduced and potential sources of faults recognized and removed instantly. In any case, SIMATIC Ident will help you benefit from greater efficiency in logistics, material management, production and service.

Radio or optical – the application decides

Depending on the application in question, one of two main technologies is used in the industrial environment: Radio frequency identification (RFID) based on radio waves or optical code-reading systems for the recognition of 1D codes (barcodes), 2D codes such as data matrix codes (DMC) and optical character recognition (OCR) of plain text. These extremely reliable technologies ensure the gap-free traceability of products and components along the entire manufacturing, purchasing or dispatch process. By choosing SIMATIC Ident, you are opting for an integrated portfolio for industrial identification – ranging from code readers and RFID systems to the integration software.



Services and support

Siemens offers field-proven concepts for process instrumentation and analytics from a single source, providing you with development continuity and a high level of security.

Our services range from consulting and engineering, connection to the control system and comprehensive after-sales services:

- System and schedule planning
- Complete design planning and engineering of the field devices
- Consultation on the selection of process instruments and analytics
- System documentation
- Installation, testing and commissioning
- Comprehensive after-sales service

Service around the world

Plants must function reliably around the clock. Efficient and effective process instrumentation and analytics are an indispensable prerequisite to this end. You also need to be certain of fast and competent service from your supplier. Siemens is a global company that reacts locally. Whether you require consulting, quick delivery or installation of new devices, the Siemens network of specialists is available to you around the world, whatever your location.

Service around the clock

Our online support system offers rapid, comprehensive assistance regardless of time or location. From product support to service information, the online support of Siemens Industry Automation and Drive Technologies is your first choice – around the clock, 365 days a year.

www.usa.siemens.com/pi-service

Legal Manufacturer

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