Solutions for optimum infrastructure in the pharmaceutical industry.
Know-how and capacity for every size of project

The experience we have gained from our global commitment to the pharmaceutical industry demonstrates one thing: we understand your needs. We know how optimal solutions are implemented. Moreover, we have the capability to encompass everything from compact clean room solutions to major projects, guaranteeing consistently high quality standards long-term. With these qualifications, our relationship with our customers is based from the outset on trust, a crucial factor in successful collaboration.

A total concept for all requirements

Under the concept "Excellence in Building Infrastructure" Siemens Building Technologies creates secure conditions that comply with all the regulations – in research and development, production, logistics and management. We enable pharmaceutical companies of any size to concentrate successfully on their core business. We focus on the entire life cycle of your systems, from building automation through building safety and security to all-round fire protection.

Time to Market:
For early launch of your products

We know that after years of research and development and once product certification is complete, you have no time to lose. You need to get your new product on to the market as quickly as possible.

Effective collaboration begins with us speaking your technical language. In us you will find partners who are familiar with the international trading strategies of the pharmaceutical industry. We also provide substantial time savings through accelerated system planning and design. Our solutions are designed so that potential modifications are incorporated right at the planning stage, and our coordination guarantees reliable operation across the boundaries of building automation systems.

Flexibility:
Fast and reliable both short- and long-term

The market decides when a production system needs reorientating. It then becomes a question of reacting immediately to the changes required.
The way our solutions are designed enables the functionality of a system to be extended at any time. Systems can also be converted quickly and easily. The openness of the system architecture offers the added convenience of allowing any combination or integration of third-party systems. It goes without saying that migration concepts from Siemens guarantee long-term investment protection.

**Compliance based on GAMP:**
*The key to successful validation*
Validation is the key requirement for production in the pharmaceutical industry worldwide. We realize its importance and have therefore incorporated the GAMP directive into our professional quality assurance.

Our active participation on various GAMP committees keeps us up to date on current validation methods. And thanks to our expertise and experience, we also influence how these are developed.

During the validation process our employees guide you through the entire life cycle of the systems, prepare the documentation and perform the qualification tests.

The reduced number of SOPs also makes everything easier for you, as we restrict human operation to what is strictly necessary. Where human intervention does occur however, handling is done in the simplest possible way. This facilitates changes to the system and reduces training costs.

**Security and fire protection:**
*Ruling out unacceptable risks*
Your security requirements go far beyond protection of life. When years of research have been spent on a medicament, intellectual property also has to be protected. What is more, only continuous plant operation can keep a market permanently supplied.

Siemens does everything to protect you from serious damage in these areas. Based on surveillance and control installations to prevent sabotage and espionage. Early detection of sources of fire and explosion. Prevention of false alarms. And alarm, evacuation and extinguishing systems should an incident occur despite every precaution.

**Benefits to you at a glance:**
- Reduced project risks thanks to integral solution concepts and project management across building automation systems.
- Qualified assistance and support during validation.
- Consistent process quality at the highest level.
- Documented proof during the entire life cycle.
- Flexible and efficient changes of application and extensions.
- Optimized infrastructure availability.
- Risk-based safety and security for know-how, infrastructure and employees.
Optimum conditions for stringent requirements

Pharmaceutical processes are extremely demanding in terms of quality, product development and manufacture as well as product storage and distribution. Demonstrably correct environmental conditions are therefore of paramount importance for these processes.

As soon as a changed parameter affects the quality of your products, fully documented evidence of the correct environmental conditions has to be provided.

The parameters also have to be precisely controlled, 365 days a year. High air change figures and sensitive regulations for individual rooms in a clean room area therefore place extremely high demands on the necessary systems.

Qualification and validation of these systems and maintenance of their valid status highlight these special requirements in the pharmaceutical industry.

Product and system selection: Everything the pharmaceutical industry needs

Siemens Building Technologies offers you a comprehensive product range for the pharmaceutical industry – from calibrated field equipment through programmable automation stations to management level 21 CFR Part 11.

Our product development is audited by leading companies in the pharmaceutical sector at regular intervals, with equally regular success. This proves that the development of our systems is totally attuned to the special requirements of the pharmaceutical industry.

21 CFR Part 11: Total compliance

We cannot relieve you of responsibility for compliance with the requirements of 21 CFR Part 11. However, the integrated technical functions in our systems make this work much easier for you.

Integrated audit trail functionality, special back-up and archiving routines and electronic signature support are just a few examples of our all-round compliance with the regulations.
Process documentation:
Your data integrity is guaranteed
Electronic recording of operating data is an essential part of the production and storage of pharmaceutical products. Our solutions meet the highest standards for data storage in a secure environment. All manually amended database entries are automatically recorded. This means you can check at any time who altered what value when and what the original value was.

The solutions provide a quality attribute which includes information on the reliability of all archived data. And this value provides information on the reliability of each individual data element in the archive. This means that defective sensors, voltage interrupts or limit value infringements can be precisely identified.

Validation:
GAMP-based support
The term "validation" was defined by the FDA in 1987 as "the provision of documented proof that a process produces a specification- and quality-compliant product with a high level of probability long-term". This definition has become a guiding principle at Siemens.

We actively assist in the validation of your production systems, providing all the related services from complete documentation to performance of all the qualification tests.

Certification:
For measurement precision and repeatability
The regulations of the FDA and other authorities define specifications concerning the quality of measurement data. The starting point is always the same: the quality of the sensors used.

The environmental conditions must be maintained within very narrow, clearly defined tolerances. Full traceability to the national and international standards must also be guaranteed.

Siemens’ extensive range of certified sensors meets the requirements for a stable environment. And as far as the operation of your systems is concerned, we support the valid status of the sensors with a special recalibration service.

Benefits to you at a glance:
■ Precision control, adjustment and monitoring of your critical room data.
■ Optimized validation costs and maintenance of validated status across the boundaries of building automation systems.
■ Compliance with official regulations and industry standards.
■ Maintenance of product integrity and documented proof.
■ Guarantee of efficient operating safety.
■ Promotion of economic viability and energy efficiency.
Excellence in Security: Because security is paramount.

For people and assets, business and production processes
Security is an increasingly important issue for pharmaceutical companies. Besides protection of people and assets, operating security requirements also cover business and production processes. Protection of substances in raw material stores or during handling in a sterile environment, or protection from contamination in the filling and packing division, to give just a few examples. Our integrated security solutions are designed specifically for each security zone.

Networked complete solutions instead of individual measures
The focus is on electronic complete solutions that cover the whole cycle from risk analysis through design and system integration to operation and maintenance of an alarm center. A crucial factor here is the incorporation of security solutions in higher-order processes. Through integration in the existing IT infrastructure or in the building control system for instance. Siemens Building Technologies also assists with planned swapping out of your security processes.

Perimeter surveillance: Site control is vital
If burglary attempts are to be detected as early as possible, the protection concept has to start with surveillance of the area surrounding the building. Perimeter surveillance employs mechanical devices such as fences and barriers as well as electronic detectors and monitoring systems.

Peripheral surveillance: For the weak points in a facade
Peripheral surveillance applies the protection concept to the exterior of the building. Appropriate detection measures give early warning of attempted break-ins, stopping intruders in their tracks at vulnerable points such as entrances, windows or lightshafts.
**Video surveillance:**
*Nothing can hide from a camera*

Only by operating total visual surveillance can a security service be present in several places at once and correctly assess an incident, e.g. in sterile production areas. This enables it to observe an incident closely, document it and take action as necessary. The focus here is on event and object surveillance both internally and externally.

Various transmission techniques and image storage systems enable interactive monitoring of all relevant incidents in a company from a central office.

**Access control:**
*Access only for authorized personnel*

By controlling access to a building or to particular floors, areas or rooms, authorized access is fully documented, substantially reducing the risk of unauthorized access, to archives or labeling and packing areas for instance. These systems can also be linked to intruder alarm systems and video surveillance systems.

**Volumetric surveillance:**
*Secure rooms, areas, floors*

By focusing on any definable "room" such as a store or archive, the movements of intruders are captured quickly and securely by alarm systems and documented in terms of authorized or unauthorized access.

Intruders normally have no time to carry out their plans. This prevents or at least significantly restricts damage.

Modern movement or infrared alarms are also capable of differentiating between typical and atypical phenomena, so that only genuine alarms are triggered.

**Object surveillance:**
*Access yes, access no*

In the case of particularly protection-worthy objects with a high value concentration, in sterile production areas or anaesthetics store-rooms for example, additional protection of the object itself pays off. Unauthorized attacks are immediately identified and the alarm is triggered.

**The management system:**
*When the alarm sounds each step is coordinated*

Danger signals and detected incidents are securely transmitted to your in-house control center, or in the case of outsourcing, to an external control center, and clearly displayed. This gives task forces an overall view of the alarm situation, enabling them to initiate the scheduled actions immediately.

Management systems from Siemens have an open, flexible system architecture, which connects different subsystems of the security technology with the building technology as required. The system architecture also allows connection of security solutions from other providers.

**Benefits to you at a glance:**

- Reduced project risks thanks to integral solution concepts and project management.
- Comprehensive solutions for building, room and object surveillance.
- Permanent alarm management with incident-specific interventions.
- Organization of workshops to evaluate risk factors and formulate security concepts.
- Servicing and maintenance on site or online via remote access.
- Alarm processing on site or through outsourcing to our own or other alarm centers.
- Where required, we take on responsibility for the entire operation of the security systems.
We employ fire protection specialists
Centered on complex production processes and store-rooms containing hazardous products, the pharmaceutical industry places extremely high demands on fire protection systems.

Reliable fire protection is also extremely important. Firstly it is vital to detect a fire as early as possible and initiate countermeasures immediately. Secondly false alarms cannot be tolerated: they not only reduce confidence in the alarm signal but more importantly cause costly production stoppages.

Fire protection systems from Siemens Building Technologies meet both criteria. In every building fire protection begins with a risk analysis by our experienced specialists. This is followed by advice and planning concerning the protection measures required as part of a comprehensive solution.

Compliance with all required guidelines
Fire protection is of prime importance for the safety of people and company property, and this is especially true of pharmaceutical companies. Most countries have quite rightly introduced strict standards that require maximum safety precautions in order to prevent fires.

However, although fire protection systems can be standardized to a large extent, requirements still differ widely in practice. It’s good to know that fire protection systems by Siemens comply with all the relevant standards.

The fire detection system:
Fast as lightning and immune to deception
When reporting fires, intelligent analysis processes detect smoke and flames immediately and reliably, even in extremely difficult ambient conditions. Fire alarms base on different technologies can be optimally programmed to the conditions in which they are deployed, and reprogrammed as necessary. Wireless fire detectors are also used for flexible extensions or for fast and simple new installations.

Excellence in Fire Safety:
Alarm – when it’s really on fire.
Gas detection:  
Risk of explosion nipped in the bud  
To prevent a fire or explosion hazard arising in the first place, Siemens’ highly sensitive gas alarms immediately and reliably identify any concentration of flammable gases in the air. The scheduled countermeasures can then be initiated without delay. These include stopping further gas leakage, regulating ventilation and if necessary calling out the fire service.

The alarm and evacuation system:  
Help arrives, everyone else leaves  
Fire protection once again demonstrates the effectiveness of clear and unambiguous communication in a crisis. An electro-acoustic or voice-controlled alarm and evacuation system always proves to be the safest solution. Clear fire alarm signals and concrete instructions help to prevent potential panic.

Obviously the whole system also functions on emergency power, with several immediate backups for loudspeakers, amplifiers, voice memories, control processors and cables.

The extinguishing system:  
Conservation, not more destruction  
Each deployment site calls for an individually adjusted extinguishing method when fire breaks out – dry, wet, foam or a combination of different extinguishing agents.

Base on this range of options we define a suitable extinguishing strategy according to the place of installation, such as the IT center, warehouse, high-tech laboratory or administrative area. Everything possible is done to prevent the extinguishing process creating any further damage in a fire situation.

The fire protection center:  
Intervention calls for coordination  
The individual components of Siemens fire protection systems have all the features and interfaces needed for networking. This allows consistent integration of all the technical safety elements in a fire protection center, providing safety officers with a complete overview at all times in an alarm situation, so that they can immediately initiate the necessary targeted intervention measures.

Benefits to you at a glance:
- Comprehensive solutions for customized fire protection systems.
- Earliest possible fire detection.
- Maximum prevention of false alarms thanks to individual algorithms.
- No production stoppages through false alarms.
- Servicing and maintenance on site or online via remote access.
- Siemens a recognized innovation leader in fire detection.
Risk analysis: Because security can be planned
According to the standard, security is “the absence of unacceptable risks”. This means that people are aware of the risks in detail, can assess their impact and the probability of their occurrence and also know the detection probability.

Our trained experts help you assess all your security and GxP risks and prepare safety concepts for you.

Implementation: From design to commissioning
Converting your ideas into real solutions is our core business. The optimum solution is devised and reliably implemented on the basis of your requirements. We are aware that special procedures such as change control and clearances are necessary in the pharmaceutical industry.

Control: Qualification and validation support
When it comes to qualification, we prepare all the necessary documentation for our systems on request, based on your individual specifications and company standards. We operate in accordance with the GAMP 4 standard. We also perform the necessary tests during IQ and OQ and carry out factory and site acceptance tests as required.

A professional partnership takes you further
Our relationship with pharmaceutical companies is extremely important. Apart from a high level of system availability, you also expect a lot from the supporting services. Project management has to be teamwork.

Added to this, the protection of your investment depends directly on the reliability of your partners. Our goal is to support you as a partner through every phase of the life cycles of your systems.

Project launch: Concept and feasibility studies
Setting the right course is important, particularly in the planning phase. Many architectural decisions affect the whole infrastructure of the property. This is why we offer our assistance and experience during this initial phase – for the right concept choice in building automation, security and fire protection.

Services from Siemens: As individual as your requirements.
Operating efficiency:  
Our Compliant Academy takes care of this  
It is important for your employees to have precise procedural instructions and training in systems operation.

We help you prepare SOPs and train your employees to operate and maintain the systems, either on site or at our own training centers. On top of this we offer certificate-based seminars covering technical issues through to the principles of validation, qualification and 21 CFR Part 11.

Alarm management:  
Because suddenly every minute counts  
All building automation and danger management systems are centrally monitored and controlled around the clock.

Alternatively a company can receive and process alarm messages itself or forward them to an external alarm center. It is also possible to transmit an alarm directly to the fire service or the police.

Our alarm systems provide every assistance to internal and external task forces to help them take the correct action. We also provide a genuine alarm guarantee, in other words only genuine alarms are triggered.

Servicing and maintenance cycles:  
A prerequisite for reliability  
Servicing and maintaining products and systems at regular intervals guarantees their reliability and also increases service life.

Material maintenance, performance tests and optimizing maintenance cycles also cuts system down-times. This is done for example by combining scheduled maintenance of fire alarms with recalibration of their room sensors.

System development:  
Our systems develop alongside yours  
Your systems must always remain state of the art, implement use changes efficiently and undergo continuous optimization. Such modifications are subject to change management in the valid environment. Our experienced service technicians know what it means to operate in the GxP environment.

Employee training:  
Training for your own security  
We train responsible employees in the management and maintenance of the security systems installed. Individual training programmes on assessment of risk factors and conduct in alarm situations yield maximum benefits when it comes to security matters.

Decommissioning:  
Data archiving guaranteed long-term  
The end of your system’s life cycle raises the big question: what do you do with your data? Your production system may not need it any more, but in certain circumstances your stored production data still has to be available for years in a valid condition.

We assist with secure archiving of your sensitive data and help with migration to other platforms or formats.

Benefits to you at a glance:  
- Ongoing support for security and investment protection during all phases of the system’s life cycle: planning, design, installation, qualification, operation, maintenance and decommissioning.
- Expert knowledge gained from over 1,000 projects worldwide in the pharmaceutical industry.
- Know-how transfer through active memberships of the ISPE and our own involvement on GAMP committees.
- Field information and exchange of experience in the Siemens Building Technologies Pharma User Club.
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The information in this document contains general descriptions of the technical options available, which do not always have to be present in individual cases. The required features should therefore be specified in each individual case at the time of closing the contract.