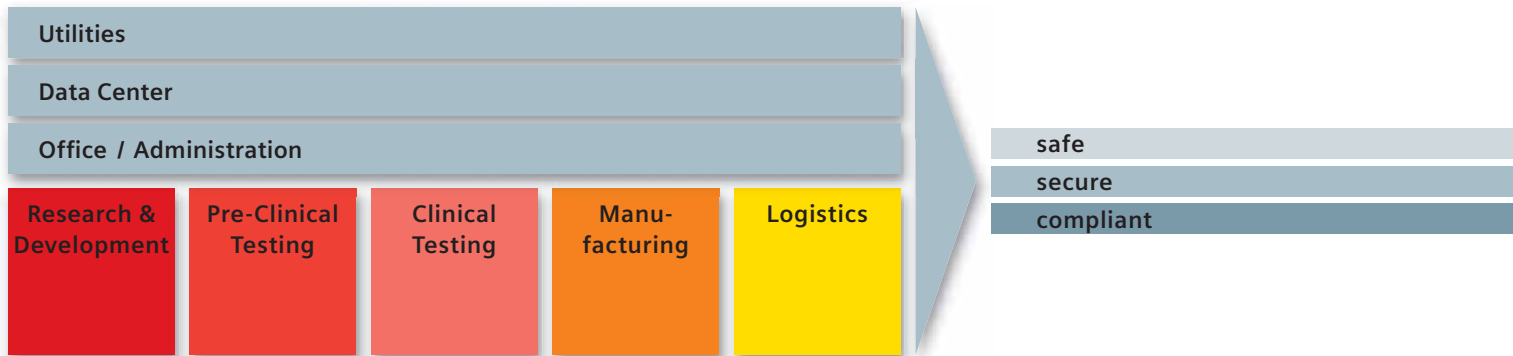


# Solutions for your successful Life Science Environments



# Building the Future of Life Science Environments



## Safety. Security. Compliance. Vital factors for creating your successful life science environments.

Excellent environmental conditions are required to achieve sustainable success in the life sciences industry: safety to protect people working with toxic substances, security to safeguard assets and unique knowledge and compliance to fulfill regulatory demands. Siemens is your reliable partner to provide safe, secure and compliant environments at each step of your value chain.

### Changing environments but similar needs

Although the life sciences value chain has special needs, one constant remains: the environments must be safe, secure and compliant. Features such as providing a safe environment for employees, securing information and compliant quality are mandatory and not a matter of choice for the success of a life sciences company, regardless of the size. Siemens combines its unique solution portfolio for these three success factors with decades of experience and knowledge in this industry as well as the successful completion of hundreds of projects worldwide.

### Dynamic processes require flexible environments

Each step in the life sciences value chain is important for creating a structure that is not only state-of-the-art, but supports future investments. Our flexible and scalable systems are easily adapted allowing a company to change and grow as the situation demands, thereby protecting its investment on a continuous basis. Flexibi-

lity allows quick migration and extension without losing sight of functional design. Documentation throughout the entire life cycle ensures efficient compliance. Our life sciences solutions let you focus on your core competence with confidence.

### Your partner throughout the entire life cycle

The life sciences industry is confronted with numerous unique challenges, including sophisticated research and production processes, time to market for new products, and investor risk, just to name a few. As a strategic partner with the perfect balance of technology and industry know-how, we provide the level of support required from your industry. From concept to building maintenance, data administration to archiving, Siemens is your reliable partner for a successful environment throughout its entire life cycle.

# Life Science Environments without unexpected Side Effects

safe  
secure  
compliant

- Planning
- Engineering and commissioning
- Qualification and validation support
- Service during operation and maintenance
- Energy services

## Fire safety

Protects life and property

- Fire and gas detection
- Extinguishing systems
- Evacuation systems
- Danger management

## Security

Safeguard assets and investments while controlling business processes

- Access control systems
- Video surveillance
- Intruder alarm systems
- Supply chain security

## Building automation and control

Compliance, energy efficiency and comfort

- Heating, ventilation and air conditioning
- Laboratory control
- Monitoring systems
- Building management

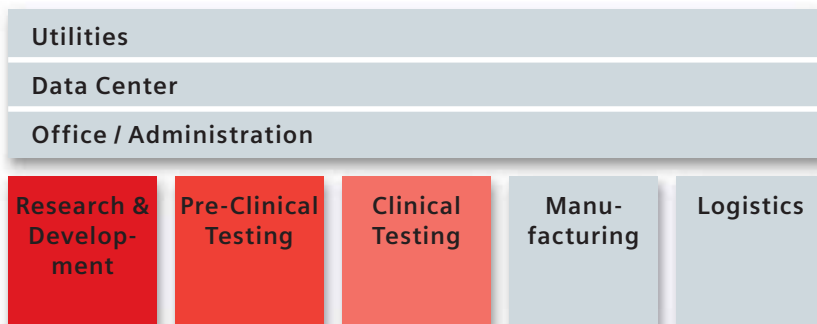
**Avoid unexpected side effects with individual but proven solutions based on years of application within the life sciences industry.**

We provide a broad solution portfolio for all aspects of technical building infrastructure. You gain valuable access to our in-depth proven industry knowledge thanks to a constant focus on your structure's entire life cycle. Our broad solution portfolio covers every stage of a project, building a strong, solid base of excellence. Our dedicated specialists focus on the entire supply chain – from

the planning stage, execution and qualification to operation and maintenance. The scalable system platforms are designed for and with the assistance of the life sciences industry.

# Behind closed Doors: Solutions for Research, Development and Testing

safe  
secure  
compliant



**Environmental conditions during the research and development stage are critical to laboratory operations.**

A careful balance between temperature, humidity, and lighting requirements for each and every part of the research and development atmosphere and comfort, health and safety needs of the occupants must be struck.



## **Safety first – for people and assets**

Proper airflow conditions eliminate the risk of cross contamination and keep people safe from potentially toxic substances. Systems for precision lab rooms and fume-hood maintain airflow and pressurization within critical spaces. Differential pressure is tightly controlled to ensure proper airflow throughout the facility. Our alarm systems detect fires as early as possible and are even capable of distinguishing between various sources of flames, smoke or deceptive phenomena. Precision gas detectors sense flammable or toxic substances and trigger an increase in the air exchange rate to exhaust and dissipate the concentration of hazardous fumes.

Evacuation is initiated no matter what with automatic voice messages distributed throughout the building, escape routes are opened and video surveillance helps verify that everyone escapes uninjured.

**“Our goal is to discover new active ingredients that help fight disease. This means frequent work with substances which may be toxic or flammable. Safe environmental conditions enable us to focus on what matters most – our work.”**



safe  
secure  
compliant

#### Siemens highlights for research and development facilities

- Integrated fume-hood and laboratory control systems for more safety, comfort and controlled energy consumption
- Convenient security solutions based on RFID for access control, IT-security and shared functions
- Comprehensive fire and gas detection for toxic and flammable substances combined with the appropriate extinguishing and evacuation solutions

#### The full spectrum of the Siemens Group offers

- Integrated Laboratory Information Systems (LIMS) and enterprise-wide business systems

#### Security – everywhere, all the time

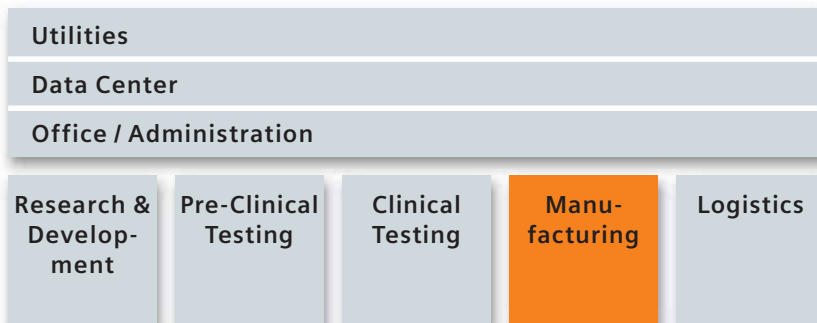
Smart restricting physical access keeps work flowing, allowing laboratory personnel to perform daily activities and processes without disturbances. A comprehensive security system guarantees physical access to only properly authorized personnel. Integrated RFID-functionality embedded in our smart access cards conveniently fulfills security requirements remotely and reliably. In addition, our smart card technology may extend to other tasks such as E-mail encryption or even paying for lunch at the local canteen.

#### Rules rule – compliance

Environmental conditions maintained by building automation and control and security systems directly impact research results. In other words, compliance is mandatory. Years of experience in the life sciences industry means that you can rely on our systems to comply with global GxP-regulations as well as local fire and insurance regulations. We apply regulatory requirements such as Good Laboratory Practices (GLP) and protection of Electronic Records and Electronic Signatures (ER/ES) to the entire building management. Siemens comprehensive validation support is your surety for efficient and effective validation, including user training and services during operation and maintenance to maintain a validated state.

# Solutions for Manufacturing Environments

safe  
secure  
compliant



Under 7/24 production environments, every breakdown, deviation from operational specifications or non-compliance issue cause significant damage.

The dedicated Siemens solutions meet the unique demands from pilot plants to large scale production sites for drug and blood products, biotechnology production and the manufacturing of medical devices – encompassing the entire life sciences industry.



## Safety – intelligent detection you can trust

By its very nature, clean room and production environments face extraordinary safety challenges. Flammable agents and the high rate of air exchange mean the danger of fire is ever-present. Yet the disastrous effects of a false alarm in terms of interruption and recovery time are almost as serious as if real fire occurred. As a result, our systems rely on multiple detection criteria patented evaluation technology capable of sensing the presence of a finite amount of smoke, providing immediate early stage detection when immediate notification and response is essential.

### Siemens highlights for GxP-manufacturing facilities

- Scalable solution portfolios designed for the regulated industry
- Security solutions to control potential impact caused by people
- Comprehensive validation support based on GAMP and dedicated validation tools

### The full spectrum of the Siemens Group offers

- Process instrumentation, process control and Manufacturing Execution Systems (MES)



safe  
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compliant

“Customers trust their health and well-being to our products. We must provide an uninterrupted supply of our products while ensuring 100% regulatory compliance and quality. Unexpected events cause downtime, which is why reliable environmental conditions are critical for each and every product.”

#### **Security – organized and optimized**

A multifaceted security system in the clean room environment reduces the risk of inadvertent contamination by personnel and deliberate product tampering. Optimized flow of all personnel through the application of various criteria can restrict access based on previous product exposure and training records. Our systems accurately integrate access control servers, human resource records, facility and equipment maintenance records and even historical access trends in order to determine whether individual access can be granted at any given time. Continuous video surveillance reliably monitors processes, procedures, personnel flow and intrusion. Video records are safely archived for immediate review at any time.

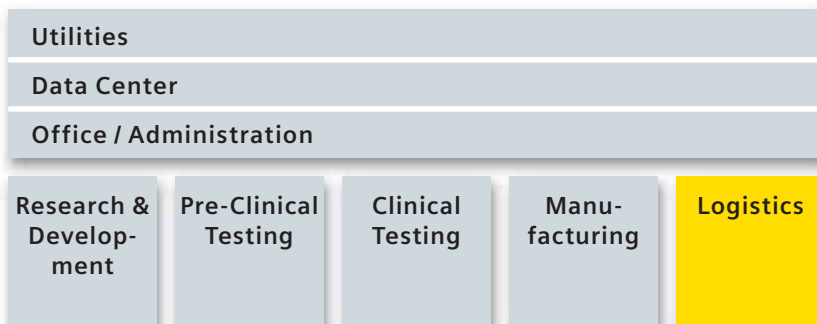
#### **Compliance – ensuring 100% drug quality**

Active contribution in and with ISPE and GAMP groups means that our specialists are able to assist you evaluate site-specific impacts on product quality for the entire infrastructure. This includes not only building automation and control and access control systems but ongoing operations such as monitoring environmental conditions and securing archived data. High-tech system architecture provides the foundation for providing secure and reliable monitoring and control for the entire infrastructure as well as sophisticated data management tools.

Procedural elements complement technology by integrating compliance assessments, the validation and execution protocol design, Standard Operating Procedure (SOP) development, and calibration services. Flexible applications ease future expansions and migrations, ultimately growing as a company’s needs grow.

# Solutions for Warehouse Environments

safe  
secure  
compliant



**A smart warehouse is one that seems to know how valuable its contents are.**

Large volumes of open spaces must house various types of raw material, packing material and product. A secure warehouse must incorporate a multifaceted storage system that not only keeps materials safe but also eases the logistics of moving the precious cargo.



**Safety under special conditions**  
Warehouse areas are an extreme risk for the quick spread of fire, smoke or heat. Losses associated with fire can be catastrophic ranging from loss of stock or even forcing the closure of a company. The height of a storage area makes conventional fire detection unsuitable. Traditional sprinkler systems are ineffective in extinguishing warehouse fires and cause significant pollution concerns once applied to fighting a fire. Water is a potential hazardous substance in its own right when exposed to certain raw materials, causing adverse and even explosive reactions. Siemens solutions focus on the safe and effective means to extinguish fires and eliminate hazardous situations.

**"All raw materials and finished products are stored in our main warehousing facility. Tightly controlled temperature and humidity conditions are essential for ensuring the stability of the finished product. In addition to crucial environmental conditions, extreme control and security measures must be taken to deter theft."**



safe  
secure  
compliant



#### Siemens highlights for logistic environments

- Environmental monitoring using integrated Mean Kinetic Temperature (MKT) algorithms
- RFID-based supply chain security for local and global logistic processes
- Air sampling smoke detection technologies for warehouses
- Broad integration capabilities for third-party systems

#### A warehouse – secured like a safe

Often certain goods must be quarantined, facilitating a need for perfect environmental conditions within a particular section of the warehouse. Our security solutions for warehouse environments include applications that track movement through the use of RFID transponders. These transponders automatically communicate when a tagged product passes through a selected area. An alarm is triggered if the movement is unauthorized.

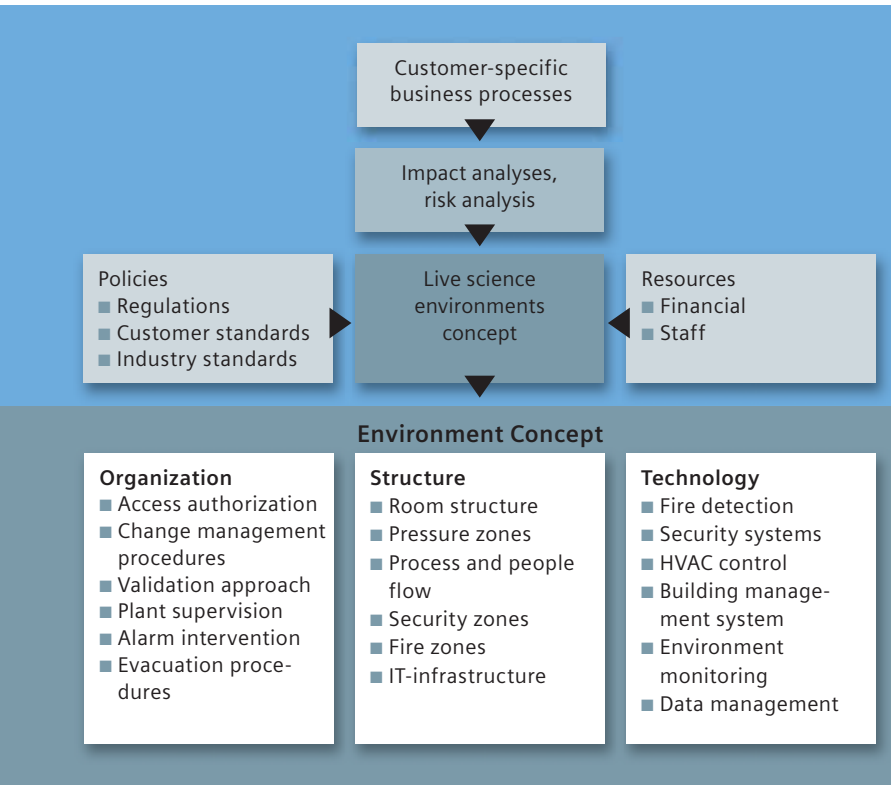
#### Supply chain security for global logistic tasks

International security regulations and risks associated with the manipulation or loss of goods during transport demand innovative solutions for container and supply chain security. Siemens RFID-based container security solutions are GPS-based (Global Positioning System) and allow “point to point” or real-time verification of your container status all over the world: from the point of containerstuffing and intermodal transport, to customs clearance and delivery at your customers distribution center.

#### Compliance – for stability and control

Raw materials and finished products of a life sciences company require strict environmental controls at all levels. Delicate sensors within the structure are installed to avoid the irreversible effects of the wrong temperature or humidity level. Large open rooms present unique challenges to the ventilation system that provides homogenous air conditions and prevents different air layers. Documented evidence of environmental conditions is needed for identification and batch protocol. Siemens environmental monitoring solutions are designed to provide documented evidence of stable conditions as well as batch traceability while the integrated Mean Kinetic Temperature (MKT) function enables the accurate calculation of environmental impact on quality.

# Increase your Immunity to Risk



## The Siemens promise: We are your reliable partner throughout the entire life cycle of your facility.

Your success is based on the exact combination of organizational measures, the proper environment structure, and its ability to fit your current and future needs. Together, we investigate site specific business processes and form building and system concepts with your needs in mind.

## The right combination guarantees sustainable success

Whether planning a new site or expanding an existing facility – we work with you to maximize your options taking advantage of our knowledge. The result is an environment concept that covers the regulatory aspects, industrial and company standards, as well as available resources.

Working with your specialists, we examine the possible impacts of the building structure on product quality and assess GxP, business and security risks.

Your individual solution is composed of technical systems developed for the life sciences industry and operational measures required to integrate your building and IT-structures.

## The future proof solution concept

The conceptual groundwork established during the planning stage not only helps us assess your current requirements, but further allows us to plan for the future of your facility. Changes, expansions and migrations and their potential impact are structured into the solution with future goals in mind. During design, engineering and installation stages you can be sure that our execution procedures meet the needs of the industry and efficiently support validation activities. System integrity tests, calibration, base lining and SOP maintenance as well as training for your operational staff.

# Prescription for successful Life Science Environments

## The Siemens solutions portfolio for the life sciences industry is unique and comprehensive.

Decades of global project management, application and specialist knowledge give us the edge when it comes to creating solutions for your life sciences facility.

### Protect your investment with systems that work for you

- State-of-the-art technology platforms and integration functions protect investments
- Proven and audited software standards reduce project-specific validation efforts
- GAMP-influenced, proven development life cycles prove: our systems can be validated
- Solutions developed with and for the life sciences industry including compliance with 21 CFR Part 11

### Reduce your project risks with our GxP execution processes

- Dedicated process for the execution of GxP projects
- Comprehensive tool support with Siemens' Electronic Validation Tool EVT
- Ongoing internal and external audits of field organization and development
- Trained, knowledgeable team of specialists

### Simplify your operations with services for the entire life cycle

- Modular service program tailored to your precise service needs
- Dedicated services for compliance consultancy, business continuity and validation review
- Reliable system and data migration combined with risk evaluation and change management
- Impact and risk analysis for site extensions and modification

### Talk with a partner that speaks your language

- Global network with the life sciences industry and constantly updated knowledge
- Unique customer relationship and experience exchange through the Siemens Pharma User Club (PUC) for over 10 years
- More than 100 members involved in ISPE- and GAMP-special interest groups
- Quick turnaround of best practices and solutions with specialists worldwide

### Rely on life sciences specialists

- Training programs focused on the life sciences industry
- Modular programs covering a wide range of facility systems
- Continually updated to give our team and customers the edge

### Trust through strong backup support from our competence centers

- Define and develop the proven solution portfolio
- Analyze regulatory demands and transfer them to the life science environments
- Support the global project execution and validation services
- Develop SOPs for processes and system platforms



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The information in this document contains general descriptions of 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.

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