

A photograph of several technicians in white cleanroom suits and masks working on a large, complex piece of industrial machinery in a cleanroom environment. The scene is brightly lit, and the technicians are focused on their work. The Siemens logo is overlaid in the top left corner of the image.

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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. The document contains a general product overview. Availability can vary by country. For detailed product information, please contact the company office or authorized partners.

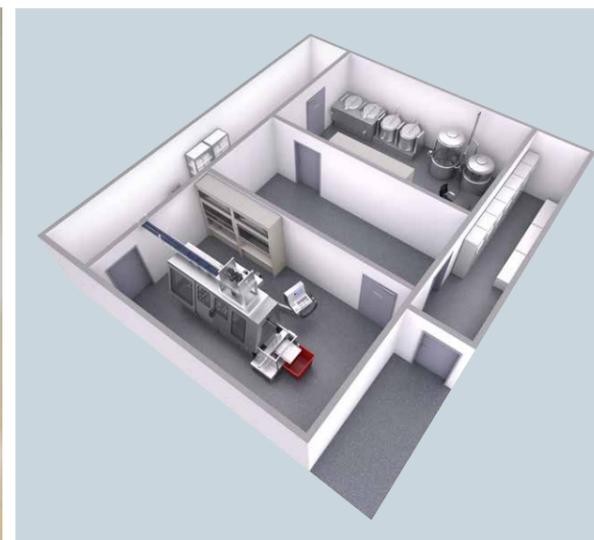
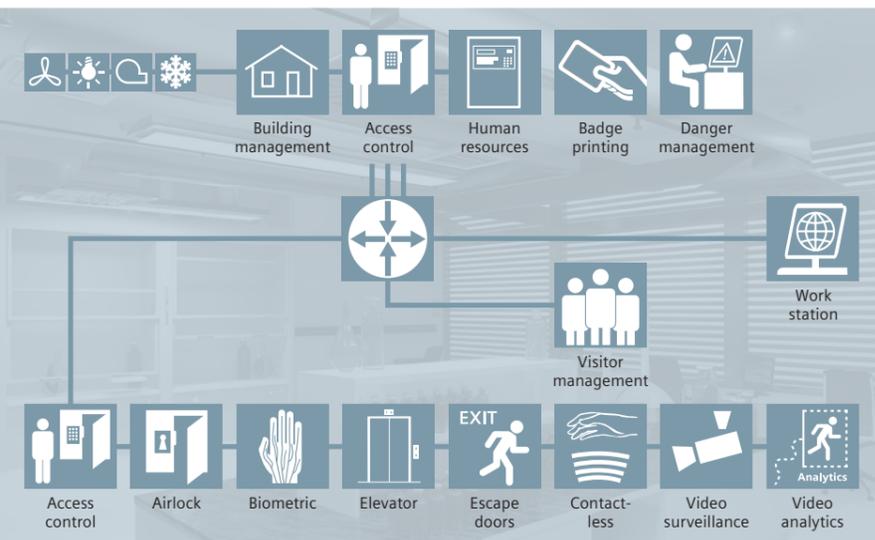
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Prevention of cross-contamination

Reduce risks to protect staff and assets, and to ensure
business continuity and regulatory compliance.

Our world is undergoing changes that force us to think in new ways: demographic change, urbanization, global warming and resource shortages. Maximum efficiency has top priority – and not only where energy is concerned. In addition, we need to increase comfort for the well-being of users. Also, our need for safety and security is constantly growing. For our customers, success is defined by how well they manage these challenges. Siemens has the answers.

“We are the trusted technology partner for energy-efficient, safe and secure buildings and infrastructure.”



The cross-contamination prevention solution from Siemens can be used to manage and control access to secured areas based on the specific requirements of each industry.

Integrated security solutions to prevent cross-contamination

Cross-contamination can interrupt production processes and cause excessive damage and unnecessary costs. That's why it's important to provide your clean room with a high level of security.

Security solutions from Siemens are tailored precisely to your clean room's requirements, offering maximum protection against risks of cross-contamination.

Contamination of goods and products manufactured in clean rooms is a major concern in the healthcare, pharmaceutical, chemical, food & beverage and micro-electronic industries. Excessive damage, unnecessary costs and loss of reputation are typical consequences caused by contamination.

Cross-contamination, i.e. the contamination of an ingredient or product by another material or product, must be avoided under any circumstances.

In addition to technical measures such as physical barriers, airlocks and pressure cascades, organizational measures such as separation in time during campaign production as suggested by Good Manufacturing Practices (GMP) should be considered.

By controlling and managing physical access to restricted zones such as clean rooms and sensitive production areas, cross-contamination prevention solutions

from Siemens help customers follow adequate predefined procedures and minimize the risk of cross-contamination by people, processes, facilities and equipment.

Clean room security solutions from Siemens strictly limit access to the secured area to authorized and trained personnel. Using electronic card keys, badge access is required for both facility entry and exit, people flow is strictly controlled and lockable auditable records log and securely store any changes and events.

Contactless access control solutions avoid contamination by using long-range readers for doors to open and close securely, automatically and quickly without any physical contact. The minimum and maximum number of persons or duration in an area can be specified according to customer and regulatory requirements. Visitors, including specialized cleaning personnel, require approval by an authorized staff member to enter the facilities.

An airlock must be accessed first before entering any other area in the clean room facility. The airlock consists of at least two doors that are interlocked in such a way that no two doors can be opened simultaneously.

A combination of special timing functions, logic sequences or a specific traffic pattern prevents unwanted passage between different areas so that cleanliness and safety are maintained at all times. The HVAC system maintains constant comfort conditions in the airlock and ensures the correct air pressure gradient is retained before it sends door release information through a standard, open protocol (OPC, BACnet) to the security system. Indicator lights and card reader displays inform employees about the door and airlock status to protect staff from any potential hazards.

In the pharmaceutical industry in particular, sites are often set up to host multiple production lines in the same building or campus. With a cross-contamination prevention solution from Siemens it is possible to define the sequence in which those separate production lines can be accessed, along with times to be considered before entering another production line. The time spent by an employee in production facility can easily be supervised.

The solutions also support the implementation of very specific scenarios. For example, only one person is allowed to enter the clean room at any given time or a person is only allowed to enter the clean room together with another person (two-man rule).

To meet additional requirements of high security zones, video surveillance verification can be deployed and interfaced with a central control room for continuous supervision. Video recording can be started automatically when the building automation solution triggers a critical alarm. Additional sensors can be integrated to allow for tailgate detection at doors and airlocks.

For comprehensive traceability, further analysis or compliance requirements, all events, including configuration changes and operator IDs, are securely logged in a system database. All entries and exits are time- and date-stamped and password-protected and cannot be modified by anyone as per FDA guidelines (21 CFR Part 11).

To ensure the ongoing reliability of the solution, Siemens also provides the required support services.

Highlights

- Limit access to restricted areas and the clean room complex to authorized and trained personnel
- Utilize common scenarios (maximum length of stay or access limited to specific times of day or a minimum number of persons) or more advanced scenarios (such as two-man rule)
- Easily manage and control the sequence of entering different areas/clean rooms
- Benefit from detailed audit trails so your solution can be audited for compliance with ER/ES regulations such as 21 CFR Part 11 or EU Annex 11
- Integrate the solution into building automation or danger management systems