

## Complete solutions for secure clean rooms

For sensitive, valuable goods, the clean room is at the heart of production. Any contamination by substances such as dust, microorganisms or smoke can disturb the sensitive production processes and negatively impact on product quality. Ensuring personal safety is also a major challenge. Active agents in pharmaceutical production facilities, dangerous pathogens in a security lab, flammable cleaning substances and toxic chemicals in a semiconductor plant are all fundamental safety risks for staff and the environment. Although potentially dangerous they are nevertheless unavoidable components within the processes and, as such must be reliably brought under control.

It is widely acknowledged that safety is never absolute. According to a generally accepted definition (ISO/IEC Guide 51:1999), safety is the absence of unacceptable risks. Consequently, companies and organizations must identify and evaluate all potential risks, as well as define and continuously review the levels of acceptance. The ISO 31000:2009 standard provides the necessary methods for managing all possible risks. Project-specific sources of danger can be determined by analyzing and evaluating the risks. These risks can be managed with a sufficient combination of organizational (e.g., processes training), structural (room and facility structures) and technical measures. Due to high-risk substances and processes or the most stringent quality standards, clean room environments in particular must meet extremely strict requirements when it comes to personal safety and product and environmental protection, as illustrated by a number of examples.

### Effective explosion prevention

Gases and solvent vapors can produce a dangerous explosive atmosphere, due to their significant potential for ignition. Special installations and specific fire and gas detection solutions are required in these explosion-hazardous areas to alleviate

such risks, as well as for controlling, regulating and monitoring the HVAC systems and process equipment. A gas detection system must reliably detect the anticipated flammable gases before the minimum explosion limit is reached, and it must alert people, display the location of the danger and take action to prevent fire or explosions. Installing a gas detection system can remove or relocate an explosion-hazardous zone in a building under applicable explosion protection regulations.

### **Comprehensive fire safety**

A fire in a clean room is the single greatest risk. Short-circuits, spontaneous ignition or leaks in containers of highly flammable or self-igniting fluids or gases are typical causes of fire. Damage to equipment and installations resulting from fire can generate consequential losses of millions of dollars within minutes. Even small fires can cause considerable damage.

Once a fire is detected, safety shutdown procedures are usually triggered automatically. This has a significant impact, particularly in clean rooms, since shutting down ventilation systems and closing fire dampers means that the pressure cascades can no longer be maintained, which can cause uncontrolled cross-contamination in the rooms. Products can no longer be used and under certain circumstances toxic substances may escape from controlled zones. It may be several days before a clean room can be placed back into active operation, for example for sterile production. A fire detector that triggers a false alarm has serious potential consequences similar to those of a real fire. Experts therefore advise maintaining a high level of safety in clean rooms. Preventive and active fire safety measures are particularly important.

### **Reliable fire detection**

The reliability of an alarm in detecting genuine fire incidents rather than generating false alarms, along with the amount of time that passes between the outbreak and detection of a fire, are key to a reliable fire safety strategy. Rapid early detection minimizes process interruptions and avoids secondary damage. Clean rooms need to have high air exchange rates, rapid air velocities and directed airflows in order to minimize particle concentration. Particles are flushed away with clean air. However, a consequence of this approach is that it is much more difficult to detect a fire, since these high airflows mean that ceiling-mounted fire detectors are susceptible to

detecting the fire at a much later stage, often at a point when damage has already occurred. Reliability and early detection can, though, be increased. Fire detectors can be provided with special clean room parameter sets that are designed specifically for clean environments. Additionally, in order to detect smoke at a very early stage, room air samples are actively extracted at suitable points in the clean room. These samples are analyzed to distinguish reliably between smoke, dust, and steam particles.

Once a real fire hazard has been detected, it is critical to take immediate action tailored to the situation. Modern and efficient clean room solutions therefore integrate fire detection, voice alarms and extinguishing systems. This allows direct interactions and enables the person in the control room to monitor alarms, events and system malfunctions, as well as to operate all systems uniformly in real time.

### **Efficient fire extinguishing**

The substances used in clean rooms create specific risks that influence the choice of a suitable extinguishing solution. Water cannot always be used as the extinguishing agent and, even if it is, special measures must be adopted, for example to reliably collect contaminated water once it has been deployed in the extinguishing process. Protecting clean rooms is a major challenge due to their impermeability, complex air circulation patterns and the necessary pressure cascades. The high risk of fire, combined with the significant value of certain equipment, means that object protection is the most commonly employed extinguishing solution. Safety cabinets (barrier isolators), for example, are provided with an autonomous object extinguishing system in order to monitor critical zones separately and to immediately trigger extinguishing in an emergency. Inert gases are preferred for this purpose. These gases are chemically neutral and generate no reaction products when the extinguishing agent comes into contact with the fire. This means that the extinguishing agent does not damage or contaminate the equipment or goods produced – a clear advantage in protecting clean rooms. Certain inert gases such as nitrogen and argon are also non-toxic, colorless, odorless and tasteless, which is especially important in the pharmaceutical and food and beverage industries, both of which are big users of clean room environments.

**Orderly evacuation**

If a particular danger is detected, such as a fire, it may require immediate evacuation of the building or the threatened areas. Once again, clean rooms present special challenges, since it is important not to release toxic substances during evacuation. It may also not be possible to effectively extract these substances. Due to these specific requirements, voice evacuation systems are an effective solution. They use visual and acoustic signals, as well as spoken language, to inform personnel of the current situation, transmitting clear instructions to the clean rooms detailing the correct action to be taken. This guarantees the safe and orderly evacuation of the clean room and adjacent areas. Additional safety warnings and clear instructions can also prevent contamination caused by the arrival of investigation or fire fighting teams.

Protecting employees, product quality and the environment are fundamentally dependent on the environmental conditions. Clean room environments in particular require the best technical protection strategies without compromising product protection and personal safety. Only those companies that reliably protect their employees and assets can ensure long-term safety and successful production. Comprehensive clean room solutions integrate all the building systems for regulating, controlling and monitoring clean rooms. In doing so, they minimize risks over the long term, increase efficiency and ensure verifiable conformity with the applicable regulations. This approach maximizes safety and ensures high system synergies that continue to pay off year after year.

**Single-source solutions**

A comprehensive safety concept can help maintain a reasonable level of safety. The Siemens Building Technologies Division offers this type of concept from a single source: comprehensive fire and gas detection, specific extinguishing solutions for room and object protection, extensive experience with explosion-hazardous areas and additional safety through innovative voice evacuation, to name just a few examples. Additional safety systems such as video surveillance and access control equipment can further enhance clean room protection. The Siemens clean room solution is based on proven and qualified elements for GMP-compliant environmental conditions, from room pressure regulation and interlock control to

comprehensive monitoring of all GMP-critical parameters. As a competent solution supplier, Siemens supports individual projects from the concept phase to shutdown, and can draw on a wealth of experience from over 2,000 completed clean room projects.

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