Design considerations for cleanrooms and controlled environments

Airtight cable and pipe seals for biopharma, semiconductor, and battery plants

Roxtec

Contents

Roxtec – a global safety solution provider

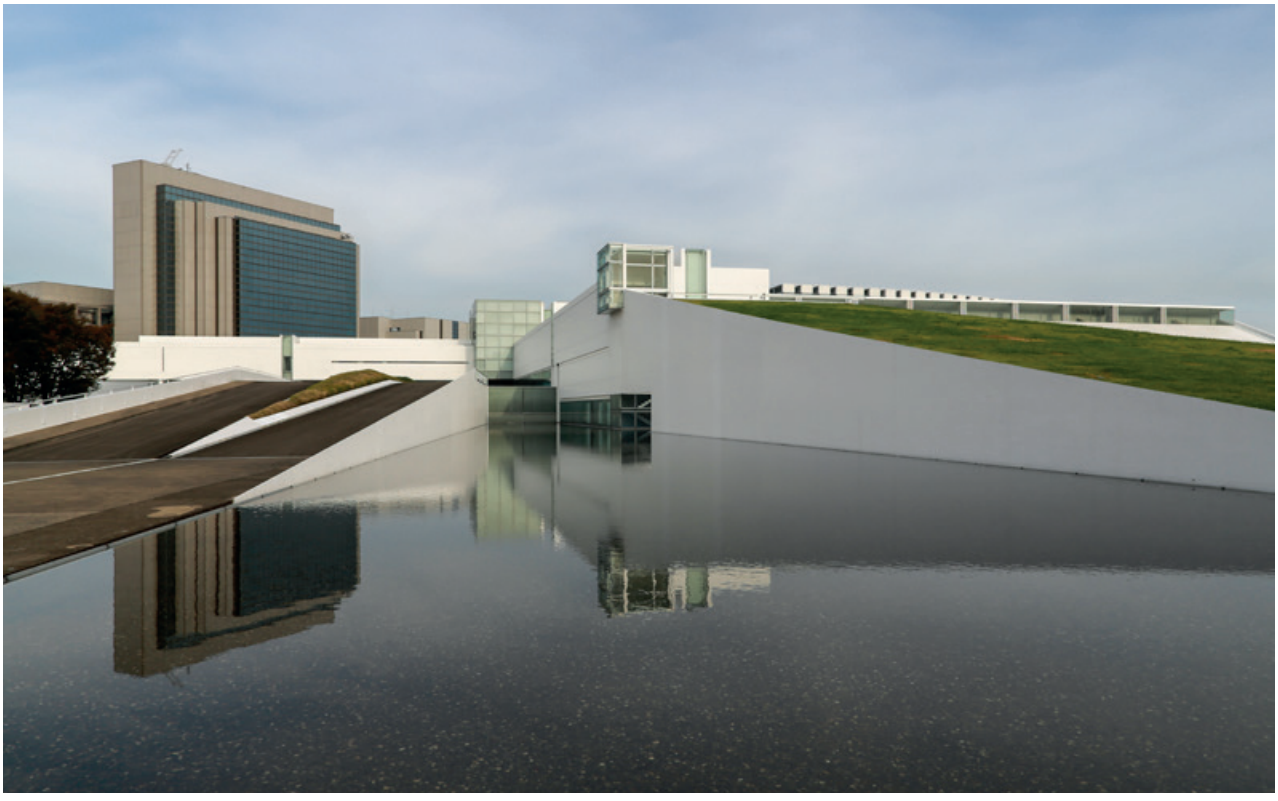
Roxtec serves and supports customers worldwide with modular-based sealing solutions for cable, pipe, and conduit penetrations as well as technical expertise and digital solutions for design, construction, and safe operations. Roxtec transits protect against multiple hazards and make a difference in demanding industries and challenging projects. The sealing system ensures safety, efficiency, and operational reliability. The Roxtec invention for flexibility, Multidiameter™, is based on sealing modules with removable layers and ensures perfect tightness around cables and pipes of different sizes.

Headquartered in Sweden and with subsidiaries around the world, the Roxtec group is built on customer focus. Roxtec has extensive R&D resources, a fire test lab and further testing capabilities for use in the product development and pre-certification process as well as for the customization of sealing solutions.

The challenge of keeping plants dry and clean

Designers of cleanrooms and containment rooms within the biopharma, semiconductor and battery sectors must always consider airtightness. The risk of costly damage or fatal incidents is far too high. Air leakage can cause everything from negative effects on equipment and downtime in the production to danger to people and society due to the escape of harmful substances. Furthermore, inadequate cable penetrations will lead to increased costs for air handling. The accumulated costs will be substantial from years of inefficient operation. However, in industries where manufacturing takes place in closed spaces with particularly high requirements, such as in biopharma or semiconductor plants, there is no single standard for cable and pipe transits when it comes to tightness but a collection of project specific requirements. It is common to have an overall requirement for the entire building, and then ensure the combined impact of materials and components stays within this requirement level. On the other hand, there might still be demanding areas having their own specific requirements. Designers must consider both general requirements and specific requirements regarding material selection, layout and sealing solutions. The requirements on sealing solutions for cable and pipe penetrations may thus vary considerably from industry to industry and from application to application. It is nevertheless crucial to identify all possible hazards – and to use the sealing solutions that meet the required certifications and standards for an overall good balance between cost, safety performance, and operational reliability.

In this technical paper, you get an overview of the most common requirements in this type of demanding environments as well as recommendations on how to seal cable and pipe penetrations for complete airtightness.



Airtightness – the main concern

Mechanical solutions for cable and pipe sealing must prevent passage of air, gas, smoke, humidity, and water through the sealing system. Airtightness is crucial in dry rooms to ensure safe and cost-efficient operations. It is related to high costs to operate at very dry conditions and any leakage of unconditioned air into a room requires dehumidification to a very low level at very high costs.

Air permeability is the ability of a system to prevent air from passing through. Testing of the cable and pipe transit can be done by subjecting it to negative and positive air pressures and monitor the leakage ratio with a flowmeter. The tightness requirements for cleanrooms vary depending on cleanroom types and the requirements are defined for the whole cleanroom and not individual components like cable penetration seals. Thus, there is no specific requirement to be applied on cable transits. It is still possible to use the requirements for the room as a guideline for the product development testing.

The test standard EN 1026:2016 describes the air permeability testing for windows and doors. This test standard methodology is applied to penetration seals even though the requirements for tightness are generally higher compared to typical requirements for windows and doors. Air tightness testing is then done later on the whole cleanroom or building to quantify the combined leakage of all penetrating elements.

The Canadian biosafety standard gives a prescriptive test for maximum air leakage in terms of pressure decay for selected BSL-2 and all BSL-3 and BSL-4 zones. The acceptance criteria include two consecutive tests with a maximum loss of 50 percent of maximum operational pressure over a 20-minute period.

All cable and pipe transits must be tested for tightness to ensure that the technology itself is tight when properly installed. The transits are one part of the full equipment and material in a room that keeps an exact and constant level of humidity and air pressure. Test reports show the test results and shall be provided from the manufacturer.

Roxtec airtight cable and pipe seals

Roxtec sealing solutions cover the different demands. Roxtec GH transits, for example, have been tested for air permeability in accordance with EN 1026:2016 (Windows and doors – Air permeability) with some minor adjustments to correspond to a cable transit. The product was placed in an airtight rig, positive or negative air pressure was applied, and the air loss was measured with pressures between 50 and 1 800 pascal. No significant pressure loss could be detected. Roxtec products could not be classified in accordance with EN 12207:2017 since cable transits are not listed as a window or door, but the seals surpassed the highest rating of Class 4 in accordance with EN 12207. Test reports are available upon request.

Roxtec has the advanced resources that are needed to perform specific tightness tests in line with project specific requirements.

Low humidity/ dryness resistance

Zones that require an extreme defined humidity level are demanding for all the materials used in the room. The materials, including the sealing components, must be resistant to and withstand low humidity and remain unchanged in dry areas. The components must also have undergone tests for varying climates.

The supplier of the sealing technology and materials used in demanding areas must have tested the solutions for dry resistance/low humidity resistance.

Roxtec low humidity resistance

Roxtec has the capabilities for testing in climate chambers and therefore the documentation needed for proving low humidity/dryness resistance. During 2024, Roxtec solutions are subject to tests aiming to show that they remain unchanged in dry areas. The new test results will be available upon request.

Basic principles of Roxtec transits
Roxtec sealing modules are inserted around cables or pipes in frames that are attached to the structure. The system is firmly sealed with a compression unit.

Emission of particles and chemicals

Besides requirements for tightness, the materials present in a cable or pipe sealing technology can be a delicate issue. It is important to be aware of the properties and challenges of different materials and surface treatments used. There are several aspects to consider. There is often a set of requirements for the entire building when containing boxed areas like dry spaces and cleanrooms. There are also specific requirements for the most demanding areas. As a design engineer and specifier, you need to know the requirements of the full project to be able to design sealing solutions that meet all requirements. You can only select solutions that have proven performance according to the demands of each zone of the building as well as the total of the full facility. All parts must respond to the overall requirements.

The main fear in dry and clean spaces is the release of particles and chemicals from materials in the room that may cause severe harm to people and costly damage to goods produced. The manufacturer must control the total level of particles and aim for materials that do not release particles, at nano level. Each material in a space releases different types and numbers of particles and this must be documented and controlled. The level of particle release sets the strictest requirements for the materials used.

Another fear is the emission of gases and chemicals from the products (outgassing).

The supplier of cable and pipe seals must be able to provide test reports for the levels of particle release and outgassing from all materials showing that they meet a certain level. The supplier have to provide documentation, account for all contents and indicate whether materials contain toxic or other hazardous substances.

ISO 14644-1:2015 establishes air purity classifications for cleanrooms and clean zones based on airborne particle concentration. Testing of Roxtec sealing solutions, using cleanroom-optimized materials and design, has demonstrated the achievement of ISO Class 4 classification.

As Roxtec seals restrict the number of emitted particles from the product and at the same time ensure airtightness, they are suitable for demanding cleanroom environments.

Roxtec particle release testing

Roxtec is a world leader in cable and pipe transits and Roxtec products have hundreds of registered certificates, tests, and approvals. For cleanroom applications, Roxtec has performed tests regarding particle release. The results show that Roxtec cleanroom-optimized solutions can achieve specific ISO class cleanliness levels applicable for demanding cleanroom environments.

Roxtec generally conducts outgassing tests in accordance with ISO 16000-9, a standard method for evaluating the emission of volatile organic compounds from building products. Typically, Roxtec applies the M1 emission classification criteria for building materials. It is important to note that outgassing criteria for cleanroom environments often vary across countries and industries and can be more stringent than the M1 requirements. Given this variability, Roxtec recommends reviewing its detailed test reports for comprehensive results. Should there be concerns about other specific contaminants not included in the reports, Roxtec is always committed to engaging in discussions about how to conduct additional testing to ensure the products do not compromise the specific cleanroom environment.

Condensation

Condense inside a dry space or a cleanroom is a risk to the operation. Condensation occurs when air containing water vapor encounters a surface at a temperature below its dew point. Dew point simulation analyses can be conducted to assess the necessity for measures to mitigate such condensation risks in dry rooms.

Roxtec condensation simulations and calculations

Equipment and components passing through barriers – including cables, pipes and penetration seals – are special risk factors. They can become cold bridges and create areas with a temperature below dew point. Pipes containing cold media are another frequent challenge. As sealing solution provider, Roxtec can handle the pipe seal. The rest of the exposed pipe must be insulated to avoid condensation issues.

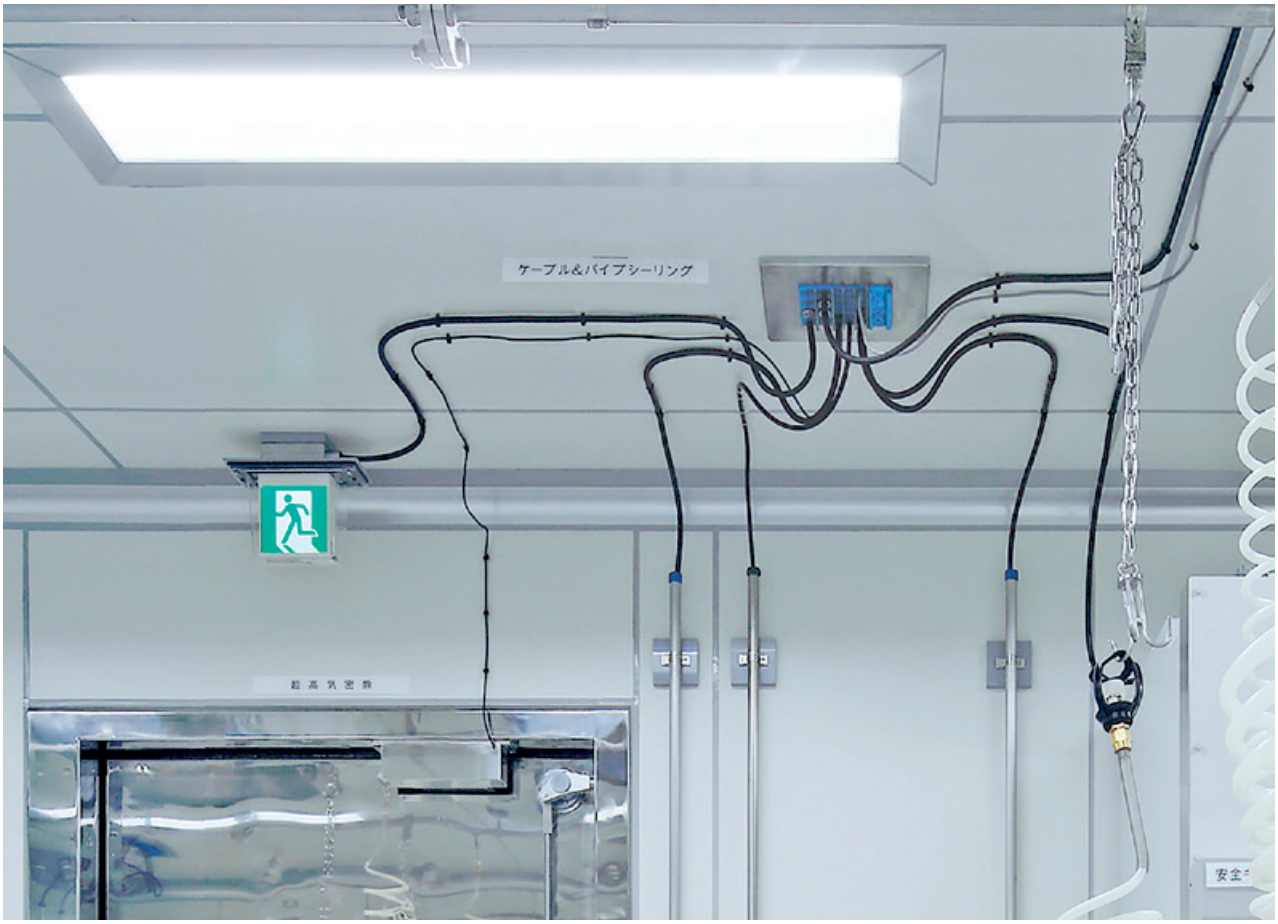
Condensation can occur if there are temperature differences on different sides of a barrier. Roxtec can simulate this, also together with intended thermal insulation materials in comparison with for example mineral wool, and calculate condensation based on the temperature of the surfaces. By doing this, Roxtec sealing experts can make a risk assessment and, if needed, present a solution.

Hygienic design

The guidelines of expert association EHEDG, European Hygienic Engineering & Design Group, are mainly used in the food industry. These guidelines on "hygienic design" can, however, be applied also in cleanroom environments. A new test procedure for assessment of open equipment was released in 2024 which affects certification of equipment like cable and pipe transits. "Hygienic design" is used for products designed for simplified cleanability, which is often characterized by high surface finish, no sharp corners, drainable surfaces, reduction of edges and offsets as well as material choice awareness. "Hygienic design" does not necessarily mean EHEDG certification. Hygienic design products can be a suitable fit anyway.

If there are substances in the air, they must not be inclined to stick to the materials used in walls and floors, including the cable transits. Suppliers must be able to offer smooth surfaces for all components. It is important to use seals where the main parts have adapted surfaces where particles or dirt cannot reside. Any screws or nooks and crannies where dirt can get stuck must be avoided as well as sharp edges, crevices, and pores. All surfaces of the installed product must be visible by the eye to be easy and safe to inspect. Gaskets should be visible, for example behind the cable and pipe transit frame flange.

Furthermore, all materials in the sealing solution must be tested and proven to withstand the cleaning process required for the dry or clean space with preserved performance and resistance.



Roxtec cleanliness hygiene and smooth surfaces

Roxtec strives to follow the existing guidelines, meet the requirements, and keep updated on cleanability test procedures. EHEDG guidelines state Ra value <0,8 µm, but the requirement can be even tougher. Roxtec offers polished stainless transit frames that meet these requirements as well as smooth surfaces and food grade lubricant. Roxtec provides frames that are installed without visible screw heads on the clean side. The frames are installed by clamping on to the wall and tightening from the back side.

Roxtec has ensured thorough insights into the EHEDG guidelines and on how to implement them. Planning is, for example, ongoing for performing development testing of cleanability in an EHEDG partner laboratory, in accordance with the new testing guidelines for open equipment that EHEDG released in 2024. This will give further verification and insights.

Roxtec has also performed successful tests regarding fumigation. The tests verify that components do not deteriorate from fumigation (chemical exposure) and include commonly used chemicals. They are available upon request and show the following results:

- Formaldehyde: 200 ppm
- Vaporized hydrogen peroxide: 750-800 ppm
- Chlorine dioxide gas: 720 ppm

Conclusion: Roxtec seals perform effectively and consistently.

Roxtec is able to customize sealing solutions based on specific requirements when certifications allow.

Fire protection

The fundamental requirement to meet for all actors in new or renovated buildings is to specify and design fire protection at the required level.

In the European Union, the fire testing and classification standards for construction products have been harmonized in European standards such as EN 13501. EN 13501 defines reactions in case of fire of a material. The European Reaction to Fire and Resistance to Fire classification system (Euro classes) is, for example, the common EU standard for assessing the qualities of building materials in case of fire.

UL is an accredited standards developer in the USA and Canada. UL standards encompass UL's extensive safety research and scientific expertise. The UL 1479 Fire Tests of Penetration Firestops. This standard is recognized by the International Building Code (IBC) in the American market and is widely accepted globally as a fire seal testing standard.

Every part of the building structure, indoor and exterior, must meet the fire protection requirements. Each supplier must be able to prove the fire rating of any material and component used.

Fire protection by Roxtec

Roxtec seals have fire ratings ranging from E15 to EI240 or F and FT, and A0 to A60 or more. The seals are, for example, fire resistance tested and approved according to standards such as EN 1366-3, UL 1479, NFPA 130, and IMO 2010 FTP Code. All Roxtec fire certificates are available on the Roxtec website. Roxtec also has ETA (European Technical Assessment) describing the product fire performance.

Roxtec has an advanced fire test laboratory used for R&D, indicative and third party witnessed tests. All Roxtec type approval certificates are issued on basis of tests conducted at accredited independent test laboratories. Roxtec transits are approved for use in A class, B class, H class and J class fire rated sections. Specific versions are jet-fire rated and approved according to ISO 22899-1:2021.

ESD – electrostatic discharge

Electrostatic discharge protection is crucial in dry rooms as low humidity increases the risk of static electricity build-up. Without enough moisture in the air to dissipate static charges, equipment and sensitive electronic components can be damaged by sudden discharges. Moreover, ESD poses a safety risk in environments with flammable materials. To prevent damage and ensure safety, dry rooms implement ESD control measures, such as grounding of equipment and the use of anti-static materials.

Roxtec bonding and grounding

Rubber, commonly used in seals and grommets due to its flexibility and tightening abilities, cannot be discharged. Cable transits are often located at an elevated position at a wall not too close to critical equipment. Rubber can be used in many cases despite its inability to be discharged. Roxtec has the awareness and expertise to recommend a solution. A risk assessment approach is recommended and the benefits of a high-performing seal should be regarded. Furthermore, Roxtec offers solutions for handling cable-bound disturbances.

The Roxtec BG™ (bonding and grounding) system combines sealing, bonding and grounding features in one transit. It provides an efficient low impedance connection to the cable armor, ideal for connecting conducted interferences to earth. Tests show a bonding efficiency level exceeding 99 percent.

The Roxtec ES (electromagnetic shielding) sealing system protects sensitive electrical and electronic equipment from electromagnetic interference and electromagnetic pulses.

Blast protection

Chemical rooms, for example where the electrode material is stored, are typically Ex classified areas. This means a potentially explosive atmosphere that implies specific certification requirements on the equipment. Ignition sources must be excluded to prevent an explosion hazard.

Blast load is a time-dependent pressure load that ramps up extremely quickly. The time range is milliseconds. The peak pressure varies significantly in different application areas.

Roxtec blast load devices

Roxtec provides Ex IIC class rated cable and pipe seals that are certified for use in potentially explosive atmospheres. The Ex rated products from Roxtec prevent the risk of explosion by maintaining the integrity and performance of the wall regarding fire protection, gas-tightness, and watertightness. Roxtec blast load tested cable transit devices limit the consequences if the worst happens. Roxtec has performed tests on both round and rectangular seals to verify sealing performance after an explosion.

The need for tightness and multi-hazard protection

Any building envelope is subject to a multitude of threats from the outside – through foundations, basements, floors, walls, and roofs. A battery cell plant, a semiconductor factory and other buildings containing sensitive operations need protection from hazards such as water ingress, gas, dirt, dust, and sand as well as reliable barriers against pests and rodents. It is mandatory to prevent flooding and humidity, and there is an absolute need for stopping fire, smoke, and electromagnetic disturbances. When it comes to dry rooms, there is also a financial risk related to any infiltration through the envelope. It is expensive to dehumidify the air in case of leakage and it should not occur repeatedly.

Also, within the building and between the different zones, compartments, and isolation rooms, superior sealing and shielding performance is crucial. There is a need for reliable cable and pipe penetration seals in floors, fire rated walls, partition walls, sandwich panels, ceilings, cabinets, enclosures, and equipment.

Selecting cable and pipe penetration seals

Considering all these varying needs and requirements, with or without any exact standard to follow, you can rely on the Roxtec expertise. Roxtec can always recommend a suitable cable and pipe sealing solution. Here are some reasons for choosing Roxtec:

- Certified multi-hazard protection of life and assets
- Tested and approved sealing materials resistance
- Flexible sealing system for efficient standardization

Roxtec cable and pipe transits provide certified passive protection against multiple hazards. The sealing solutions ensure safety, efficiency, and operational reliability by protecting against fire, smoke, gas, water, dirt, dust, sand, pests, rodents, blast load, and the risk of explosion. They prevent noise, reduce vibration, can be used for bonding and grounding of cables, and protect against EMI and MRI.

The Roxtec sealing system

Roxtec adaptable sealing modules are inserted around cables, pipes, or conduits of different sizes in frames that are cast, welded, or bolted to the structure. The frames are available for any type of structure and in different materials, such as powder-coated or stainless steel with a clean surface finish. The system is sealed with a separate or integrated compression unit. There are Roxtec sealing solutions for applications in walls, sandwich panels, floors, ceilings, cabinets, and equipment as well as for underground use. Roxtec has solutions for the building envelope and substations as well as for interior fire walls and fire cells. The seals are available for hazardous locations and bonding and grounding applications.

Easy installation and retrofitting

Roxtec seals are easy to design and quick to install and their flexibility brings additional advantages over time. You can open them to benefit from the built-in spare capacity for easy upgrades and adapt them to new cables, pipes, and conduits of different sizes. This is excellent if there are late design changes. Providing reliable cable retention, the seals prevent cleanroom ceiling cables from falling down on equipment.

When you need to perform retrofit work, you can install a Roxtec seal around existing cables and pipes. You get a uniform construction quality and penetrations that are easy to inspect and maintain.

Standardized solutions for many applications

You can use Roxtec seals to protect dry rooms, cleanrooms, anhydrous rooms, and other contamination-controlled areas as well as the entire biopharma, semiconductor, or battery cell plant. The seals protect against fires from lithium-ion runaway upon charging and the risk of explosion due to chemical reactions while being dust-tight and moisture tight to ensure a neat and dry production environment.

Securing airtightness is a smart way to control humidity, airflow, and pressure, and to manage risk and avoid costs for drying. With Roxtec cable and pipe seals, you can thereby combine reliable accident prevention with great energy efficiency performance. Using airtight seals, you can achieve an ultra-low humidity environment, save on energy for dehumidifiers, and save energy throughout the lifecycle of the building.

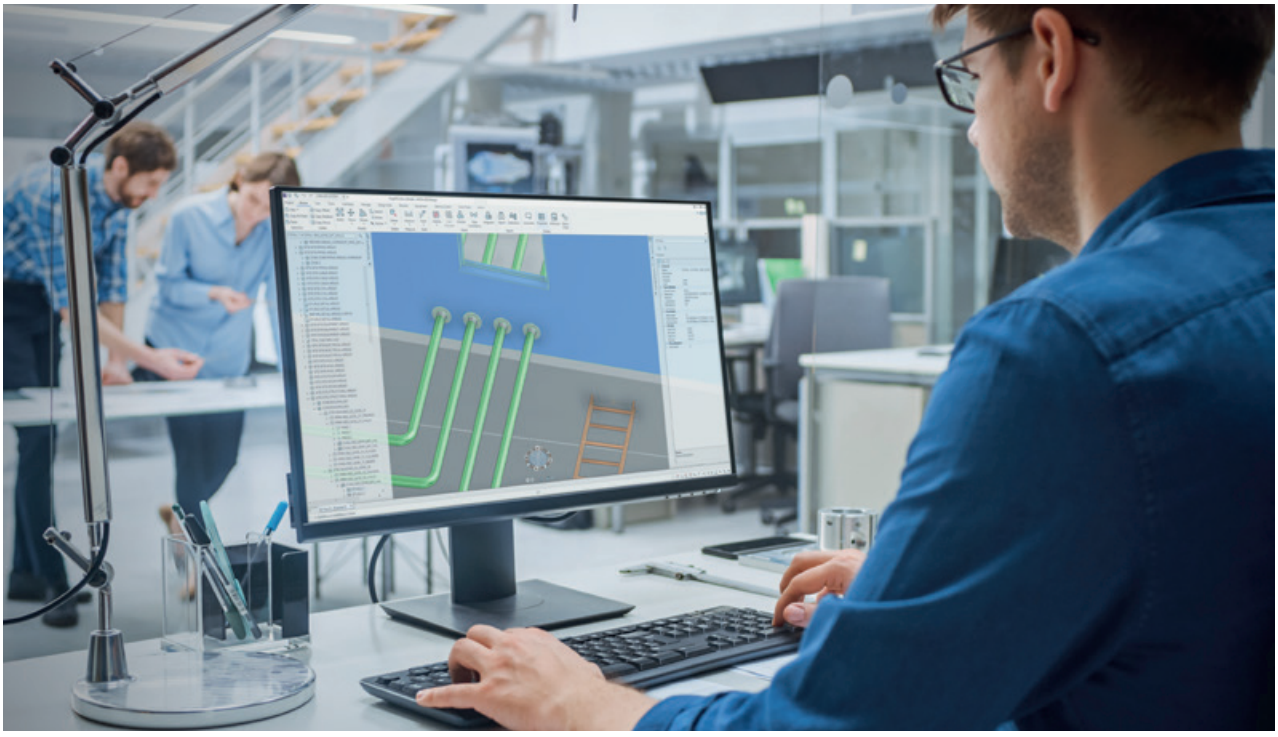
Accident prevention in manufacturing plants

Standardizing with Roxtec seals helps you meet the requirements for all process crucial areas, including battery plant applications such as electrode slurry preparation, coating and drying, cell assembly, electrolyte filling, formation and ageing, chemical storage, and substations. Roxtec modular-based seals are perfect for any dry room, from small-scale research facilities and pilot plants for scaling up production through to giga-plants for large-scale battery or semiconductor manufacturing.

Manage high cable density

You can specify Roxtec for cabinets, junction boxes and enclosures. The entry seals ensure long-term performance while helping you handle high cable density. The seals consist of few components and require less work and a smaller footprint than traditional cable glands since you can seal dozens of cables in each opening. The seals can also be used for process pipes and in installations for ventilation.

Service and support



Roxtec has the sealing expertise and a full range of services, including technical support, customization, installation training, safety inspections, and digital tools for transit design and management, to help ensuring safe operations in advanced biopharma facilities, battery cell plants, and semiconductor plants.

Software for transit management

More than 50 000 design engineers use the free software Roxtec Transit Designer™. There are examples of engineers saving months by designing hundreds of transits in just a few minutes. You can use it to share approved outputs with project teams, and integrations with frequently used design software enable access to Roxtec 3D CAD libraries and BIM objects. It is one of the interlinked tools in the Roxtec Software Suite™, which is developed to help owners, operators, engineers, builders, and installers save time, ensure quality control, and optimize safety during the construction process and throughout the entire lifecycle of projects and assets. Besides the advantages of digital selection, design, and transit management, Roxtec seals are easy to use and inspect in the field. You increase efficiency from early design through to installation and follow-up and streamline the workflow without compromising quality.

Links and references

ISO 14644-1:2015. Cleanrooms and associated controlled environments
www.iso.org/standard/53394.html

UL standards
ulstandards.ul.com

EHEDG (European Hygienic Engineering & Design Group)
www.ehedg.org

EU REACH (Registration, Evaluation, Authorization and restriction of Chemicals)
www.trade.gov/eu-reach

RoHS (Restriction of Hazardous Substances in Electrical and Electronic Equipment)
environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive_en

Contact us

Feel free to contact us if you need sealing support in any phase of the design, construction, or operation of your plant. We are always ready to share our experience and expertise to help you ensure safety.

Find your local Roxtec representative on roxtec.com

Protecting life and assets

Roxtec is the world leader within flexible cable and pipe transits. Since the start in Sweden in 1990, we have grown successfully to cover all continents. Our passion is innovative sealing solutions, and our goal is to make our world a safer place.

- Extensive R&D resources and advanced test facilities
- Inventor of Multidiameter™
- Customers in more than 80 markets

Would you like to learn more about cable and pipe seals for cleanrooms and controlled environments?

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