

Pharma & Food - Cleanroom Design: what to look out for in doors, glazing, walls and fixtures



Controlled Environment

Cleanroom Design: what to look out for in doors, glazing, walls and fixtures

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When it comes to current GMP regulations and other specifications, cleanroom requirements are clearly defined. Customer specifications, the choice of systems and the details of the design are all crucial considerations. Ronny Töpfer, Project Engineer at Glatt Ingenieurtechnik (Weimar, Germany) explains what's important in terms of walls and other associated components.



Fig. 1: Various equipment and systems installed in a cleanroom. (Source: Glatt)

In advance of any cleanroom project – whether it's a conversion or a new build – careful and comprehensive planning is essential. Before the start of any pharmaceutical cleanroom assembly, such as the interior fit-out, all structural work must be completed as fully as possible. This means that the building shell should be finished and the construction site must be completely clean. This is the only way to ensure that no particles are transferred from the surfaces of the building fabric into the cleanroom to be constructed.

Details such as the cleanroom class, how many employees will pass through the personnel airlocks and what the material flow between areas will look like are just a few of the key aspects that must be defined. Full and open communication by the client with the project planner doing the work is essential to ensure a smooth implementation. As such, cross-trade planning is indispensable. At Glatt, all the required services (HVAC, EMSR, process, black and clean media) are available in-house to ensure that every task can be co-ordinated quickly.

At least four walls – but which ones?

According to GMP requirements, all surfaces, including ceilings and walls, must fulfil several requirements. They must

- be smooth and non-porous
- be easy to clean
- be impermeable and crack-free in low-germ areas
- be effective and repeatedly cleanable and able to be disinfected
- be resistant to light
- have a low joint content
- have no horizontal and vertical deposit areas.

Making the right choice of wall elements is the first step. Among the many different cleanroom walls, double-skin elements are recommended for interior walls (single-skin for exterior walls) or sandwich (so-called monoblock) elements. Alternatively, drywalls can be used for lower cleanroom classes (non-classified, for example) with a suitable two-component coating. However, a higher level of dirt ingress during the construction or remodelling phase must be considered here.

Wall systems made of metal elements are mainly constructed according to three principles: axis grid, band grid and monoblock. They are generally selected according to the desired degree of installation in the enclosed cleanroom. Axis and band grids are the most common choices because they guarantee 100 % cleanroom-compatible and durable sealing of the surfaces – thanks to the joints between the elements being minimized. The proportion of joints is also reduced in sandwich elements.

Monoblock constructions with an insulating core and firmly bonded surface-finished metal cover layers on both sides are recommended. Galvanized steel sheets with a PE paint coating are generally used as the top layer. Depending on the supplier, wall elements can be up to six metres high with no horizontal joints or crossbars. Cutting to size on site is generally to be avoided because better manufacturing tolerances can be achieved ex works.

The double-skin wall system is characterized by highly flexible assembly and optimum installation options – all of which can be changed on the construction site or later. An additional advantage is that pipes with small nominal diameters and cables can be easily installed in the intermediate area. Special solutions such as all-glass walls demonstrate the universal system application of many manufacturers. However, the cost factor is not insignificant and loads can only be transferred to a limited extent.

No access for germs: doors in the cleanroom

Another important aspect of cleanroom planning is the doors and door systems. The three most common variants are swing doors, sliding doors and roller shutter doors. Single or double-leaf hinged doors usually consist of a tubular frame construction made of aluminium system profiles with a powder coating; they should be installed flush with the partition wall.

The doors have seals, maintenance-free hinges, tubular frame locks, overhead door closers and other options such as lowerable floor seals. Although the door or gate size is subject to manufacturer standards, they are also available in customized sizes. All-glass doors should not be used where material transport is particularly important (risk of accident if glass breaks). Sliding cleanroom doors are now available at a high technical level (including overall tightness); but they should only be used in situations where space is limited as they are more difficult to clean than hinged doors. The cost of a sliding door, which should also be automatically lockable, must also be appropriate for the intended use.

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Fig. 2: Cleanroom-compatible door installations. (Source: Glatt)

Cleanroom-compatible roller shutter doors are state-of-the-art. Although they are more expensive than swing doors, they are a viable alternative if space is limited: both the external material properties (mechanism enclosure) and the tightness of cleanroom-compatible designs fulfil all necessary requirements and function reliably.

Personnel and material airlocks

During the design phase, comprehensive insights into the work and production processes are essential for the planning team. This is the only way to determine where airlocks and clean or dirty corridors are required to protect the health of employees and prevent contamination of the final product. As cleanroom elements are generally very sensitive, it is advisable to use generous amounts of ram and scrape protection in transit areas. Here too the cleanroom market is very advanced, although these elements might protrude, they are easy to clean and comply with cleanroom regulations.

Keeping a clear view with glazed elements

Glass elements are indispensable in a cleanroom: they promote communication and the well-being of employees, provide an overview of ongoing activities and allow natural light to enter. Windows should therefore be given serious consideration in the layout from the initial planning phase onwards – although the exact position and size can be changed later. Integration into cleanroom walls should be based on a grid pattern to avoid incorporating different wall sizes.

Material pass-throughs can have different sizes and designs depending on their intended use. According to specific requirements, they should be actively ventilated or purely passive. Integration into cleanroom walls should always be flush with the cleaner side – based on the grid pattern – for better cleanability.

A planned approach

Cleanroom specifications stipulate that all cavities must be sealed from the outside to ensure they are inaccessible, diffusion-proof and particle-tight. Pharmaceutical equipment or systems often span different cleanroom classes. Here, connections to the wall or ceiling, as well as the floor in the form of flush covers or seals are required, which must be properly defined.



Fig. 3: A pharmaceutical plant showing a cleanroom and a corridor. (Source: Glatt)

One of the special features of cleanroom planning is, among other things, the integration of machinery, systems and equipment. Media, electrical and other utility lines are now integrated into the wall system as standard. To make this possible without any problems, a wall thickness of at least 80 mm has become the established norm. It is also possible to double the wall thickness or even create a separate technical area.

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No set formula

There are, of course, always special cases that will need to be modified depending on the application. This is when the experience of the cleanroom expert comes into play. The planner often needs to be the "inventor" of creative solutions because no two process sequences in a cleanroom are the same. Glatt pays particular attention to each customer's special requirements during the concept phase as part of the entire planning process. As a result, customized and tailor-made solutions can be considered and implemented. As well as being a single-source supplier of complete solutions, Glatt experts ensure that all dirt-transferring factors are removed from the shell and that the cleanroom fully meets the customer's requirements before any other systems are installed.

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