PROCESS WORLDWIDE

Cleanroom Planning

It’s All in the Details: Planning Cleanrooms, But Doing it Right!

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GMP requirements for low-particle manufacturing conditions can only be met with cleanrooms. An essential success factor for new buildings and conversions, holistic cleanroom planning with expert support brings together various engineering disciplines and interfaces to showcase why the devil is in the detail.

Glatt pharmaceutical plant in cleanroom design (Copyright: Andreas Suetterlin)

Cleanroom technology is the be all and end all in pharmaceutical production; yet, there’s a lot to consider when planning new cleanrooms, which is why, right from the start, companies that are redesigning or converting their cleanroom ideally involve an experienced planner as a partner. At this early stage, it is particularly important to define the technical specifications, URS (User Requirement Specifications), standard operating procedures and other customer-specific documents that describe and define the project criteria. Current GMP regulations and country specific requirements must also be acknowledged, so that engineering can take all requirements into consideration.

Once the “requirements catalog” for the project has been drawn up, the real challenge begins: the coordinated interaction of the various disciplines. Detailed consultations with the cleanroom experts at regular and closely timed intervals are absolutely essential. After all, every element must meet strict requirements to comply with cleanroom conditions — from electrical installations and furniture to any fixture that directly touches or penetrates the wall, ceiling or floor.

How to avoid rework

In contrast, an uncoordinated approach quickly leads to costly rework and rescheduling. And, here, the devil really is in the detail; for example, if installations are not cleanroom-compliant, they may have to be dismantled. These could be small elements, such as power outlets, monitors that were not properly integrated or process technologies in and around the cleanroom that do not comply with GMP standards. In the worst case, compromises may have to be made that are not very suitable for the cleanroom. By contrast, cross-discipline and interface-reduced planning minimizes the potential for conflict and reduces both time and costs.

Technically, every detail counts

In the cleanroom, every installation needs to be well thought out. Take the surface, for example; here, good cleanability is right at the top of the priority list, along with resistance to disinfectants, cleaning agents and input materials. Reason enough, certainly, to reduce the number of joints in the cleanroom to a minimum. If this is considered at the planning stage, wall elements can be planned to fit exactly and process equipment can be inserted precisely. The number of joints can be further reduced by a clever choice of “wall against ceiling” or “ceiling against wall” system.

Fixtures such as fully surface welded and floor-flush washing stations with no maintenance joints, or customized stainless-steel furniture, that perfectly integrate into the cleanroom and its associated process conditions are prime examples of successful planning.

The floor covering must also be carefully selected. Whether PVC, terrazzo or epoxy resin, each material has different properties. Therefore, the requirements of the specific project are critical. For example, if wet areas are involved, slip-resistance plays a key role. The degree of mechanical stress or conductivity are further criteria that must be considered during the selection process.

When planners become inventors

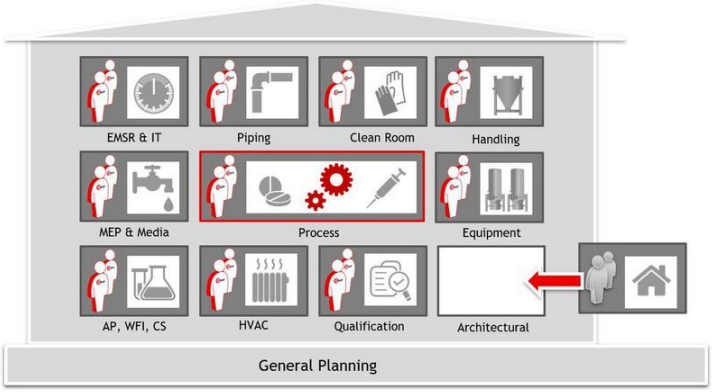
Occasionally, some elements have to be developed, designed and manufactured in-house. It's not uncommon for cleanroom planners to become "inventors" and commission particular designs from specialized cleanroom suppliers. Glatt's self-developed washing station with no maintenance joints is a good example of this. It's made of stainless steel, is fully welded and designed without silicone joints. Furthermore, it's already being used by a variety of customers. It can be integrated into almost all standard cleanroom constructions and can be used wherever the equipment has to be cleaned directly in the cleanroom.

In the pharmaceutical sector, cleanroom-compatible cold storage cells are also often required, such as for the storage of intermediate and end products. In these cells, which are usually connected to the cleanroom and sometimes also serve as a production area, accommodating the refrigeration technology can be challenging. Furthermore, planners must avoid any cold or thermal bridges and choose fixtures such as light fittings, storage shelves or floors that can permanently withstand the inherent temperatures and present the cell as a holistic cleanroom.

Overall, it's a great advantage when cleanroom designers work closely with suppliers of other components: cleanroom walls, ceilings and/or floors, as well as airlock equipment and furniture, cannot always be ordered from a catalog. There is a comparatively high need for coordination and consultation here.

The benefit of holistic planning

When it comes to the main equipment, any peripherals should also be listed and included in the planning. Partners who plan processes themselves and are familiar with the technologies used are ideal. Glatt, for example, undertakes planning for pharmaceutical and biotechnological production processes, including space-creating measures. If a company is familiar with both GMPs and cleanroom planning, this minimizes many interfaces and project risks.



Cleanroom planning as part of integrated planning from process to factory.
(Source: Glatt)

If the planning information for other engineering aspects that have a particularly large number of interfaces — such as HVAC, process equipment/piping and supply systems — are handled by one supplier, the added value is even more significant.

Another important aspect of Glatt's design services is the use of the latest CAD software for 3D modeling. BIM (Building Information Modeling) plays an essential role here and is integrated into the daily workflow. In particular, direct exchanges with the customer during the various planning phases is of great importance. Assessing collision risks within the 3D model and ensuring coordination with the architecture and construction teams are other important aspects — right from the start. After all, this is when the basis for the cleanroom to be installed is created.

No friction loss at the interfaces

Another important point, after the engineering work has been completed, is making sure the assembly process goes smoothly. If you work with an experienced partner who has already successfully implemented many small, medium and large-scale projects in different industries and cleanroom classes, and who can coordinate a wide range of disciplines on the construction site without exception, the chances of successful implementation are good.

Essentially, this means that any obstructions or damage that might occur at the installation phase can be minimized during the construction process. Glatt's many years of experience in the planning, design and implementation of cleanrooms with all fixtures and fittings, such as

airlocks, process technologies, washing stations, electrical installations, media columns or ventilation technology, is a prerequisite for fast and successful implementation.

Experience as the basis for success

Overall, Glatt has already been able to implement many cleanroom projects of all classes with areas ranging from a few hundred to several thousand square meters. No two projects are the same. Thanks to the large number of projects — from small conversions in existing buildings to major projects in the pharmaceutical sector — the company's team of experts can draw on an enormous wealth of experience and rule out errors or defects in advance through forward-looking planning.

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