

How to select a cleanroom

Modular cleanrooms for new businesses, new product development



Cleanroom Selection Criteria

Selecting a cleanroom for a new business or product is not a difficult process. There are many considerations and options, but focusing first on requirements will help make the decision-making process easier.

Rules mandated by government regulations, ISO guidelines or customer requirements are the first consideration in selecting the right cleanroom. For example, government regulation, USP797, outlines specific requirements for the manufacture of pharmaceutical products, and ISO 14644-5:2004 guidelines specify basic requirements for cleanroom operations. Most often regulations or customer specifications will dictate the cleanliness level or required rating, which provides a good starting point for choosing the right cleanroom.

Cost is an important consideration, especially if starting a new business or new product line. Prices can vary greatly from custom, fixed wall construction to modular, free-standing, soft wall or hard wall prefabricated cleanroom systems. Fixed wall rooms are typically most expensive, with soft wall rooms the least expensive. Additionally, size, shape, configuration and accessories will affect the overall cost.

The location of the cleanroom site within the existing building structure, and the number of processes and workers in the cleanroom will determine the size and shape of the room.

In addition to meeting performance needs, many companies consider the visual aesthetics of a cleanroom very important,

wanting to project a high-tech image with visual appeal to attract new customers.

Advantages of Modular Cleanrooms

Modular, free-standing cleanrooms have many distinct advantages over their fixed wall counterparts. Using modular rooms greatly reduces design, engineering and construction time, therefore reducing costs. Since they are not an integral part of a larger structure, modular rooms can be taken down and moved to other facilities, or even sold as an asset. Fixed wall cleanrooms do not have this flexibility.

take several months to construct a fixed wall cleanroom because of the amount of design, engineering and the various trades involved. However, a fairly sophisticated modular room can be constructed in a week or two. Onsite assembly of a modular cleanroom is also less disruptive to surrounding operations in comparison to their fixed wall counterparts.

Modular cleanroom systems offer potential tax advantages for businesses. They are not typically considered part of the building and can often be depreciated faster than built-in, fixed wall cleanrooms. Tax consultants can provide specific tax advantage information.

ISO Class	Fed-Std 209E Class	Maximum Number of Particles in Air (Particles per cubic meter)					
		Particle Size					
		≥ 0.1µm	≥ 0.2µm	≥ 0.3µm	≥ 0.5µm	≥ 1µm	≥ 5µm
ISO 1		10	2				
ISO 2		100	24	10	4		
ISO 3	(Class 1)	1,000	237	102	35	8	
ISO 4	(Class 10)	10,000	2,370	1,020	352	83	
ISO 5	(Class 100)	100,000	23,700	10,200	3,520	832	29
ISO 6	(Class 1,000)	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7	(Class 10,000)				352,000	83,200	2,930
ISO 8	(Class 100,000)				3,520,000	832,000	29,300

Table 1

Expanding a modular cleanroom can be easily accomplished by taking off a wall and adding another module. The prefabricated design allows the room to be expanded, relocated, or reconfigured into a different shape or made into multiple smaller rooms.

All air handling and filtration equipment modules are built into the modular room ceiling. Hookups for electrical and plumbing are engineered in as part of the design.

The amount of time it takes to construct a modular room is much less than constructing a permanent walled structure. It can

Modular, Solid Wall Cleanroom Construction Considerations

There are two basic types of modular, solid wall cleanrooms: Recirculating and non-recirculating. Product and process requirements will determine which type of room is best suited for a companies needs.

Recirculating cleanrooms recirculate the air within the cleanroom and prevent it from mixing with outside air, allowing for better control of the temperature and humidity. Air is recirculated back to the high

optimal cleanroom performance, air flow design, and air filtration. These factors are all critical to the design of a cleanroom. The design of a cleanroom is a complex process that involves many factors, including the type of work to be done, the level of cleanliness required, and the available space and budget. The design of a cleanroom is a complex process that involves many factors, including the type of work to be done, the level of cleanliness required, and the available space and budget.

because of customer, industry or government specifications. These performance requirements identify the cleanroom class

air change
rooms are
number and size

specific amount of time

Many companies may use the gowning room for transferring production material and equipment in and out of the clean environment. However, pass-through, or double-door airlocks are more efficient and keep the introduction of particulate contamination to a minimum.

Specially produced cleanroom furniture and tools should be used because they are designed for low particulate generation. For example, tables are smooth and sealed, so they don't shed particulates and can be easily wiped down.

Site Considerations

The modular cleanroom location within a building is very important. Physical space, temperature/humidity and cleanliness will affect selection decisions and overall project cost.

Most modular cleanrooms can be installed with as little as 25 inches of clearance over the inside clear height of the room on non-recirculating rooms, and about 30 inches with recirculating rooms.

A typical cleanroom should operate at about 66-70 degrees Fahrenheit to ensure a comfortable environment for workers wearing cleanroom garb such as lab coats, head coverings, gloves, and masks.

Non-recirculating cleanrooms work best when the space surrounding the cleanroom is air-conditioned. If supplemental air conditioning is necessary, it can be brought into the space above the cleanroom or directly into the HEPA filters, ensuring the room's temperature is cooler than the surrounding space.

Recirculating cleanrooms provide better temperature control between the interior cleanroom and the surrounding building space. The room air does not mix with the external air and only requires cooling to compensate for the internal heat load.

Processes requiring humidity control will require special environmental control systems and are usually only available with recirculating cleanrooms. Typically, systems are made to just add or just remove humidity depending on the surrounding environment.

On-site Installation

Installation of a modular, hard wall clean room is quick and easy. With modular systems, everything is prefabricated at the factory, so specialists are not needed to assemble the room, just local trades or internal people. It's not uncommon to start a project on a Monday and finish on Friday.

Maintenance Considerations

Regular cleanroom maintenance is very straightforward and is needed to ensure cleanroom performance and certification.

Interior surfaces are wiped down daily on a regular basis or before each shift using a solution of de-ionized water and 10% alcohol. The cleanroom floors are routinely mopped as well. Vertical surfaces, such as walls can be cleaned less frequently depending on product requirements. All contact points such as door handles and user-operated equipment should also be wiped down on a daily or shift basis, again, depending on process requirements.

HEPA filters have a pre-filter that needs to be changed regularly—depending on loading. The HEPA filter modules are fairly maintenance free, but are required to be certified every year. Additionally, proper air flow and leak checks are usually part of the regular certification for a cleanroom.

Certification of a room can be performed by either internal personnel or external companies. Most companies prefer an external, third-party firm to perform the certification, providing them with an

independent analysis. Customer or product requirements may require independent certification.

Summary

Determining the right cleanroom for a new product or business requires balancing many selection aspects—from process requirements and cost, to performance and construction. The decision process is not complex, but a clear understanding of cleanroom requirements, regulations, operation and available options will make cleanroom specification and design easier.■



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