

HIGH-PERFORMANCE DOOR SYSTEMS KEEP CLEANROOMS 'CLEAN'

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Enormous strides have been made in the pharmaceutical manufacturing arena over the generations. Gone are the days of the local pharmacist concocting tablets in his storefront for "made-to-order" prescriptions.

Today, the use of cleanrooms is essential for contamination control, and the cleanroom has evolved into a science of its own. Keeping airborne contaminants generated by people, process, facilities and equipment from entering or suspending in the environment is a primary concern to cleanroom designers. Because pharmaceutical cleanrooms are classified according to the particle concentration of the air, the right components are essential to meeting the cleanliness criteria required.

What is clean?

But what does "clean" really mean?

Consider the cleanliness status in your home. Some rooms are cleaner than others. For instance, the kitchen is cleaner than the garage. Of course the activities that take place in these rooms are quite different. When the door is open, debris and leaves collect in the garage. The kitchen is cleaner than the garage because the door to the kitchen is smaller, and the kitchen is obviously cleaned more frequently because it is used for food preparation. Like your home, pharmaceutical manufacturing facilities and businesses have different levels of clean.

Maintaining a controlled environment in which the levels of particulate, microbes and contamination of all kinds are reduced is achieved by continuously "flushing" the cleanroom with highly filtered air that is forced through High Efficiency Particulate air (HEPA) filters. HEPA filters can prevent over 99.97 percent of particles measuring greater than 0.3 microns in size from entering the cleanroom. This is incredible considering the outside air we breathe may contain up to 5 million suspended particulates of pollen, dust and smog in one cubic foot.

Even a particle as minute as a strand of human hair, will cause expensive downtime or lead to costly maintenance if discovered in the delicate balance of the cleanroom environment. Airborne particles provide a ride for microorganisms on which to produce, leading to contamination of product.

That is why keeping the cleanroom "clean" is imperative to the pharmaceutical manufacturing environment.

Doors make the difference

Whether it's a Class 100 or a Class 10,000 cleanroom, manufacturers in pharmaceutical, biopharmaceutical, medical device, electronic and other critical manufacturing industries require their cleanrooms to be simultaneously functional, flexible, economical, practical, and of course, clean. But, while the current ISO 14644-1 and ISO 14644-2 Standards still call attention to the function of air filtration and air distribution in cleanroom design, the regularity and relative consistency of these systems across manufacturing platforms has ushered in a new age of cleanroom design focused on all components of the room, including floors, walls and especially doors.

Several factors should be carefully investigated before investing in a door system solution for the cleanroom environment:

Air Pressure And Sealing - To support air filter technology, maintaining appropriate room pressure and seal is of utmost importance. With airflow levels and negative pressures in the hallway between suites, particles can travel easily and threaten the quality of controlled substances manufactured at any given facility. This is exactly why door system design should contain proper sealing to control pre-determined air circulation rates as well as reduce airborne contamination.

Cleanability – Logically, cleanroom doors are cleaned frequently. Cleanroom designers are constantly looking for cleanroom doors that can maximize cleanability, while standing up to chemical treatment. A recent study showed today's standard door materials deteriorate visibly over 30, 60 and 90 days when subjected to standard chemical

solvents. The doors that fared best in this experiment were fiberglass doors manufactured much in the way fiberglass boats are created, using durable, seamless layers with no edges or grooves. Cleanroom doors should also be manufactured with minimal ledges, crevices and angles. This inhibits dirt and bacteria from collecting easily and makes it easier to withstand frequent cleaning. Surfaces should be non-shedding, non-porous and resistant to sustaining microbial and fungal growth, as well as designed to tolerate consistent cleaning and sanitization with a number of chemicals. Some cleanroom doors are even installed without drilling into the floor. Just imagine the particulates that accumulate in the crevices resulting from floor installation and bolt-fitting, and how difficult these areas are to clean. Coupled with cleaner installation, which limits additional particulates that are released into the air, doors installed without floor drilling are better choices for cleanrooms.

Corrosion – Problems with corrosion go hand-in-hand with constant cleaning, especially with older door systems. It is not uncommon for old-style cleanroom and lab areas to be outfitted with hollow metal or aluminum doors. Painted steel or aluminum could shed particles. Eventually, these types of doors start to flake, deteriorate and sometimes virtually dissolve after being exposed to toxic and severe cleaners. This long-term corrosion problem, coupled with cleanability issues, can cost manufacturers money in the long run. When it comes to corrosion, cleanroom designers can't afford anything less than perfectly seamless door solutions for their facilities. What cleanroom designers really need to look for are fiberglass doors, which provide maximum corrosion protection with a fully enclosed panel. This investment will pay dividends in the end. Corrodibility is not only a lurking problem on the door's surface, but can also affect the door's tracks. While aluminum or galvanized tracks are a less expensive option, they are corrodible. Stainless-steel tracks, on the other hand, offer longevity, durability and the ultra-clean look companies and regulators are looking for, especially if European standards are at stake.

Flexibility and Security – Besides the cleanability and durability factors, cleanroom doors should offer various options for flexibility to fit personnel's needs as well as process requirements. Having flexible door systems enables project engineers to outfit cleanrooms with doors needing vision panels, pushplates or other activation devices, magnetic locks and interlocking systems. Utilizing interlocks, sometimes referred to as "airlocks," is not uncommon, especially in personnel entrances and exits, gowning and de-gowning areas and material transfer airlocks in cleanroom environments. The functional concept of the interlock is to prevent two doors from being open at the same time, thus preventing air infiltration from one space directly to the other. This is typically done in cleanroom environments to prevent outside, airborne contamination from entering the process areas.

Efficiency – Ultimately, the new age of cleanroom design gravitates toward greater efficiency and cost savings. Practical cleanroom design minimizes HVAC requirements, reduces cleaning and maintenance costs and withstands the conditions in which they function. By investigating in cleanroom door products with an eye toward air seal, cleanability, corrosion, flexibility and security, designers can provide increased returns over the life of their doors and the cleanrooms as a whole.

In short, cleanroom doors significantly contribute to the clean level of critical environments. There are plenty of cleanroom door companies out there. Make sure to look for a company with experience in the marketplace and proven technology and performance. Making these considerations now will make all the difference in the future.