The cleanroom door is more than just a 'movable element to close a room'

Summary

Closing a room is one thing, closing a room where products are disinfected with hydrogen peroxide in the form of a gas (VHP) is a completely different story. If that gas escapes, serious accidents can happen!
In a Controlled Environment facility you will often find different doors, such as single or double revolving doors, sliding doors, roller doors or gas-tight doors, as well as other variants. In this white paper you will be introduced to the variation of (cleanroom) doors and their specific properties.

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Introduction

As depicted in the title of this white paper, many reference books describe the door as an architectural element to close a space. This is a correct description in 99%, or even more cases. In a Controlled Environment (CE) room, however, a door has more functions than just closing a room and in any case has to meet many more quality aspects than one is accustomed to in a normal user environment.

Some additional properties or functions can be listed as follows:

- Airtight seal in different degrees
- Flush design and easy to clean or disinfect
- Self-closing or opening
- No 'product-specific' contamination by released particles when used
- Gas-tight seal
- Fire resistance
- Quick opening and closing
- Equipped with interlock closure or motion counter
- Equipped with access control or registration of persons

In order to understand that a door, for example in a cleanroom, must have above-average properties, we need to briefly examine the principle of the cleanroom itself. In a cleanroom, there is usually an overpressure regime. Differences of 15 to 20 Pa between 2 rooms are normal and too much air leakage through cracks and seams would affect the pressure regime. In a cleanroom the number of (dust) particles in the air is reduced to a certain minimum. These particles can have very serious consequences during a lithography process of approx. 15 nanometers (nm is a millionth of a millimeter!) in the semiconductor sector. In addition, these particles are also the carriers of microbiological contamination, such as bacteria, viruses, fungi, etc. Obviously pollution that can have catastrophic consequences for the pharmaceutical, health care and food industries. The smaller the number of particles per m3, the stricter the rules are (clothing and cleaning regime, code of conduct, choice of materials for structural parts, etc.).
Once the cleanroom is set to the right quality, we don't want a door, for example, to cause extra pollution. This could be caused by gears and lubricants in drives for sliding or rolling doors, or 'outgassing' (release of gases from materials) of volatile substances such as plasticizers, etc. from rubber seals or PVC material. Contamination of a room can take place in many ways, including through the doors, which is something we want to prevent at all times.

In the next chapter, we will give an overview of the various structural door variants and then briefly discuss possible inspection certificates which are often used, in particular for GMP classified cleanrooms.

Structural door variants

Hinged doors

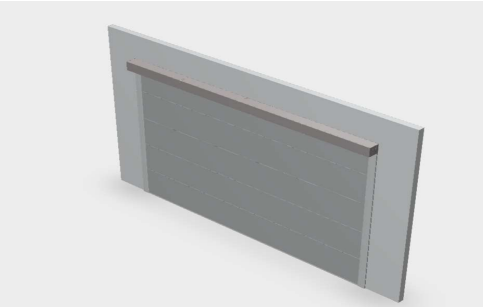
The classic hinged door is available in a single and double version, with a maximum height of 2350 mm and a width of between 630 and 930 mm. The versions may differ. In any case, the doors are at all times trimmed or molded with an impact-resistant, dimensionally and impact-resistant plastic-bonded material. Hinges and other door hardware are normally made of stainless steel or coated aluminum. In many cases, the hinges are designed in such a way that the doors can also be hung to the nearest mm afterwards. The bottom of the door is often provided with a drop seal to optimize the closure. Very frequently, the hinged doors are provided with a door closer, either recessed or surface-mounted. Doors can be fitted with glass elements which are incorporated flush. Materials from which doors are produced are mostly HPL (High Pressure Laminate) or coated steel. The interior of a door can be made of different materials such as aluminum honeycomb, plastic honeycomb and in the semi-conductor sector also high-pressure sheet material.

High-performance doors

Cleanroom high-performance doors have an almost airtight seal that reduces pressure loss and protects clean environment from pressure loss, moisture and particle contamination. Usually the retractable curtain is made of transparent PVC material with pierced strips, which can also be supplied in a silicone-free version, and a transparent strip can be placed at eye level over the entire width of the curtain for viewing or light ingress. The guide rails are made of cold rolled steel and the housing elements are made of coated steel. These can of course also be carried out in stainless steel. Motors are often fully integrated and often driven by a frequency converter, which guarantees a gentle start and stop. Fast operating speed and a good seal are minimum requirements which are usually imposed on the doors. When an object touches the door, the PVC curtain and door construction absorbs the impact and releases it from the side guides without damaging or even being damaged. Modern high-performance doors are equipped with an automatic repair system. The curtain repositions itself after a crash to reduce downtime and maintenance. The underside of the curtain is equipped with a soft edge and a safety device which ensures an interruption of the closing of the curtain in case of hindrance by people or materials. Operation can take place in different ways, such as a simple 'mushroom' operation as a push button on the wall or on the floor, a pull cord or with a remote control or via infrared motion detectors. High-performance doors can be used in GMP areas up to a maximum of the C classification!

Fire curtains

Flexible rolling fire curtains are produced with a special non-combustible fabric, rolled up on a roll-axis. The curtain automatically rolls down and the fire zone is separated in the event of fire. Control of the curtain is often directly connected to the fire alarm system. The fire curtains require little space and often offer a simple solution for 60 to 120 minutes fire retardancy in locations where sliding or hinged fire doors are not an option. The fire curtains in combination with high speed doors are an ideal solution for a fast and safe entrance into clean rooms.



Sliding doors

Sliding doors are available in many versions. The doors can be made entirely of glass and are therefore completely transparent. Steel doors are available in various colors, but are also available with a printed foil. Hermetically sealed sliding doors have been specially developed for use in sterile areas in hospitals, laboratories, clean rooms and other facilities where high demands are placed on hygiene and the control of infectious hazards. Sliding doors can be designed with radiation, sound and fire protection properties. Control of the sliding door varies from manual operation to a fully automatic door. Differences in pressure of 100 Pa are no exception in certain cleanrooms and such differences in pressure can be achieved with a sliding door in locations where there is no room for hinged doors.

Gas-tight doors

Stainless steel doors that meet the highest requirements in terms of gas tightness. Sealing is 100% guaranteed by an integrated rubber air duct, placed all the way around in the edge. Operation, control, security and interlock functions are brought together in a PLC control box. These doors are often used in locks where disinfection processes take place with the aid of the VHP (Vaporized Hydrogen Peroxide) system, primarily in compounding pharmacies or the pharmaceutical industry. Every door is delivered and assembled according to specific guidelines and is certified separately.

Certification provides certainty

There are of course many regulations to show that a clean / hygienic workspace meets specific requirements. These requirements are described for Controlled Environment facilities in, among other things, the ISO 14644-4 standard, the GMP Annex 1 (written by the FDA) and the EHEDG directive 44. In the past, the focus was mainly on air treatment and air filtration in order to meet the requirements. By now it has become clear that the materials used to build the product systems with which the cleanroom itself is built, such as wall and ceiling systems, floors as well as doors and, for example, the sealing compound (sealant), also play a major role in keeping a qualification up to standard in a cleanroom during the period of use. The qualification in the cleanroom after building it, or the annual validation, is very important in terms of checking the results achieved. Having materials or elements applied in a controlled environment tested is another process that must be carried out beforehand and gives the client the assurance that the cleanroom will meet his requirements even after the qualification has been recorded.

Of course, there are many test institutes that can provide a correct and (inter)national product certificate for a specific product. In the Netherlands, TNO is a good example of this. Overall, increasing use is being made of the Fraunhofer Institute in Germany, the largest research institute in Europe with 72 institutes and research institutes, more than 25,000 employees

working internationally and approximately 2.3 billion in research turnover. The research institute and part of the Fraunhofer institute IPA (Institute of Production and Automation) is equipped with the right equipment, ISO 14644-1 class 1 cleanrooms to perform tests and a team of specialists in the field of cleanroom technology. The certificates 'Fraunhofer TESTED DEVICE'® and 'CSM'® are internationally recognized test labels confirming the suitability of the cleanliness. Once approved, products are entered in the Cleanroom Database Certification Register http://www.tested-device.com

Several partners in the PP4C alliance make use of the Fraunhofer Institute services and have (part of) their range of certificates that demonstrate quality in accordance with the most recent Controlled Environment regulations.

Interlock

In a cleanroom, doors are more or less a necessary evil. We have to have an entrance to and from a space. If this space also has a pressure difference with the space in which we stand or come from, it is necessary that the door has a good position in relation to the pressure. The door must always be pressed in the groove and opened against the pressure! In order to keep the rooms as clean as possible, traffic between the various classified areas should be avoided wherever possible. When the door is closed, it should also close the room as leak-proof as possible in order to avoid pressure loss.

As soon as there is a transition in a GMP cleanroom with a class difference between B and C or A and B classified rooms, a lock must be installed. Where appropriate, two locks should also be placed behind each other in GMP cleanrooms to give users the opportunity to adapt their clothing to a heavier, i.e. cleaner, clothing regime.

A lock also needs to be set up at the entrance or when leaving a cleanroom and then entering a gray or black room (not clean). The same applies to the transport of materials in and out of clean rooms.

Such locks should preferably be provided with so-called 'hard locks', also called interlock closures. The interlock system requires that each door is equipped with a position switch and an electrically controlled lock. In clean environments, these devices are generally electromagnetic devices commonly referred to as 'mag-locks'. In this interlock system, both doors are unlocked at all times. When a door is opened, the position switch activates an input signal to the lock controller, which sends a signal to activate the lock of the opposite door. This opposite door remains locked until the first door is closed. After the first door is closed, the lock signal to the second door is released and both doors return to the normally unlocked status until the next input is received by the controller.

Conclusion

As has been known for a long time, at the start of a design for a Controlled Environment facility, we need to ask ourselves a number of questions and then describe in the URS what the requirements and qualifications are for the various areas in the facility. A number of questions need to be asked with regard to the subject of 'Door technology in Controlled Environment':

- Does a room need a door?
- Why does the room need a door?
- What are the requirements for the door?

If the above questions are taken into serious consideration in the design team or together with your supplier, then it will become clear in the URS where and what is required. The final design can then concretely describe which specifications are in force or which door is specifically prescribed.

ORIGIN

PP4C (Professional Partners for Cleanrooms) is a strategic alliance between a number of specialized companies. They are active in the design, construction and maintenance of cleanrooms and laboratories in a broad spectrum of market segments. PP4C is also active in medium- and high-care areas in the food industry.

White paper authors: Geerd Jansen and Olaf Buiting

Geerd is the initiator of the PP4C organization as well as General Manager of Brecon International B.V. and as such strategically involved in the PP4CE alliance.

Olaf Buiting is business unit manager of AssaAbloy Entrance Systems. AssaAbloy is the world market leader in Entrance Technology and a PP4C partner in the Netherlands and internationally active as a partner within PP4CE.

For more information, see: http: /www.pp4c.nl