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CLEAN ROOM DESIGN AND THE ROLE OF FLOORING

An overview of cleanroom design and flooring considerations to ensure regulatory compliance.

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Clean Room Design and the Role of Flooring

Working in cleanroom conditions is essential for a growing number of industries in order to safeguard process operations, the quality of components, the integrity of laboratory research or the hygiene levels of healthcare facilities. A cleanroom is defined as a controlled environment that has a low level of pollutants such as dust, airborne microbes, aerosol particles and chemical vapours.

The extent to which an effective cleanroom should maintain a contamination free space is exemplified by the fact that an average urban environment contains 35,000,000 particles per cubic metre that are 0.5 micrometres (μm) or larger. In contrast the strictest standard of cleanroom only allows for 12 particles per cubic meter and they must be no larger than 0.3 μm!

Designing a Cleanroom

Cleanrooms are cleverly designed so that the number of particles that have been brought into the room or which have arisen and been deposited in the room is as small as possible and where other parameters relevant to cleanliness, such as temperature, humidity and pressure, are tightly controlled.

There are many elements that go into making a cleanroom and they all have to work together to achieve the desired result. One of the major components that you'll find in any cleanroom is the High Efficiency Particulate Air (HEPA) filter that is used to trap particles that are 0.3 μm or larger. Some sites may even opt for an Ultra Low Particulate Air (ULPA) filter, that is able to remove 99.999% of airborne particles down to a size of 0.1 μm. It is these air filters that determine the air flow, which is a critical part of an effective cleanroom.

It is important to bear in mind that it's not just the building materials and equipment that are important, but also the working practises that are put in place. For example, personnel working in a cleanroom should be trained in contamination control theory and must wear special clothing designed to trap contaminants that are naturally generated by skin and the body.

Setting the Standard

Cleanrooms can be found in practically every industry where small particles can adversely

affect the work being carried out onsite. While they can vary in size and complexity, cleanrooms are used extensively in industries such as pharmaceuticals, semiconductor manufacturing, biotech, medical device and life sciences, as well as the critical process manufacturing common in aerospace, optics, military and Department of Energy facilities.

As we can see from the above list, a large number of the most regimented and sensitive industries carry out research, design and production work within the confines of a cleanroom – otherwise the organisation in question could risk dangerous errors and issues creeping into the process, which for sectors such as pharmaceuticals, healthcare and electronics is inconceivable.
To find out if a space can be effectively classed as a cleanroom or not we have to turn to ISO 14644, which sets out the criteria for creating and maintaining an effective cleanroom space. This benchmark specifies classes of air cleanliness in terms of the number of particles expressed as a concentration in air volume and it determines the standard method of testing to determine the cleanliness of an environment.

The importance of this standard is evident in the number of industry bodies, associations and best practise guidelines that reference ISO 14644 as the benchmark by which cleanrooms are defined. In the pharmaceutical sector, both the European GMP and FDA cGMP documents include ISO 14644 as the method for cleanroom classification and qualification while the WHO states that the ISO method is one of the primary sources for determining microbiological and particulate cleanliness. The Australian Government's Department of Health and Ageing also references ISO 14644 in the GMP documents that cover the manufacturing of therapeutic goods, which includes medicines and medical devices.

Class	maximum particles/m^3						FED STD 209E equivalant
	>=0.1µm	>=0.2µm	>=0.3µm	>=0.5µm	>=1µm	>=5µm	
ISO 1	10	2					
ISO 2	100	24	10	4			
ISO 3	1,000	237	102	35	8		Class 1
ISO 4	10,000	2,370	1,020	352	83		Class 10
ISO 5	100,000	23,700	10,200	3,520	832	29	Class 100
ISO 6	1,000,000	237,000	102,000	352,000	8,320	293	Class 1,000
ISO 7				3,520,000	83,200	2,930	Class 10,000
ISO 8				35,200,000	832,000	29,300	Class 100,000
ISO 9				35,200 000	8,320,000	293,000	Room Air

ISO 14644's Particle Allowances

The table below outlines the amount of air particles allowed in each of the nine cleanroom classes as laid out in ISO 14644, ranging from "Room Air" at ISO 9 to the rigorously controlled and close to zero particles benchmark of an ISO 1 environment.

Revised in 2015, ISO 14644's new method of sample testing, when successfully applied, assures that at least 90% of the room is compliant at a 95% confidence limit.

Algorithm For Compuation of Average Particle Concentration at a Location

$$\bar{X} = \frac{X_{i,1} + X_{i,2} + \ldots\ldots + X_{i,n}}{n}$$

$\bar{X}$	is the average particle concentration at location i, representing any location
$X_{i,1}$ to $X_{i,n}$	are the particle concentrations of the individual samples
n	is the number of samples taken at location i

The changes to the ISO standard also emphasise that the air cleanliness needs to be consistently monitored with long-term evaluations. This is encapsulated in ISO 14644-2, which states that in addition to the initial execution of a cleanroom, yearly assessments are required to make sure that the space stays at that standard.

A continuous measurement system should be used for monitoring the concentration of particles in the immediate grade A zone, and is recommended for surrounding grade B areas. For routine testing the total sample volume should not be less than 1 m^3 for grade A and B areas and preferably also in further out grade C areas.

Cleanroom Suitable Flooring Materials

One of the key elements of maintaining a cleanroom environment is the floor, as it can be a prime site on which contaminants can build up and cause problems. To ensure that the floor actively supports the objectives of a cleanroom, it is important to install systems that provide the site with the necessary cleanability and functionality properties.

The Fraunhofer Institute for Manufacturing Engineering and Automation (IPA) founded the CSM (Cleanroom Suitable Materials) industry alliance in order to provide a mark of accreditation for products designed for a cleanroom environment. The CSM qualification takes into account a long list of standards, including ISO 14644, to define the suitability of equipment or material against a specific cleanroom class based on its emission of airborne particles, biological resistance (metabolising potential and microbicidity), outgassing behaviour, cleanability, electrostatic discharge properties and chemical resistance amongst other factors.

CSM status is a critical qualification for decision-makers in contamination sensitive industries when selecting cleanroom components such as flooring.

Epoxy floor coatings are available that have been tested by the IPA. The benefit of installing a certified resin system in a cleanroom is that not only will it not negatively impact the interior air quality, but the site will also benefit from the multiple operational advantages of industrial standard resin systems.

The advantages of resin finishes includes the seamless and impervious surface that this type of material creates, which makes it very quick and easy to clean the floor area as the cleaning regime does not have to work around tricky gaps or joints. It is also easy to install coving using a resin system so that there is a smooth transition between the floor and the wall, avoiding the possibility of contaminants getting stuck along this seam.

The durability of epoxy resin solutions means that the cleanroom, whether it is a lab, processing zone or medical facility, doesn't have to worry about foot traffic, wheeled equipment, point loading, spillages, impacts and frequent cleaning affecting the integrity of the finish.

This guide has been produced to give an overview of cleanroom design and the flooring considerations that should be taken into account to ensure regulatory compliance.

Detailed recommendations and advice are available from our network of regional technical and sales representatives.

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