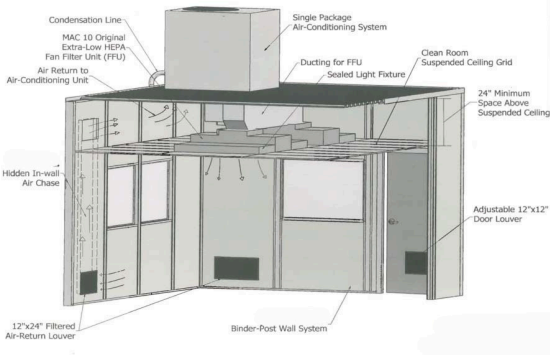
What are Cleanroom Classifications?



Cleanroom environments are essential in various manufacturing, scientific, and medical fields. For example, in the aerospace industry, manufacturers produce highly intricate parts for airplanes, such as components for engines, flight controls, and hydraulics. Since these systems are critical for keeping large aircraft airborne, the parts must be flawless.

To ensure this, a highly controlled environment is used for their production. Cleanrooms provide a solution by regulating the size and quantity of particles in the workspace. Similarly, pharmaceutical companies require controlled environments for manufacturing and packaging medicines.

These cleanrooms may have even stricter standards due to FDA regulations. To determine the level of control needed for a cleanroom, ISO (International Organization for Standardization) has developed cleanroom classifications.

Cleanroom Classification Basics

ISO cleanroom classifications are relatively straightforward to grasp. Essentially, they define the maximum number of particles allowed in a specific volume of air. The fewer particles present in that space, the higher the cleanroom class. These particles can include pollutants like vapors, microbes, or aerosol particles. A higher-class cleanroom signifies a lower risk of contamination.

ISO cleanroom classifications range from ISO 1 to ISO 9, with ISO 1 being the cleanest and ISO 9 being the least clean. These classifications follow a logarithmic scale, meaning each increase in class allows 10 times more particles in the air. For example, an ISO 1 cleanroom is the most stringent, allowing no more than 10 particles (of 0.1 micrometers or smaller) per cubic meter. At ISO 2, the limit is 100 particles per cubic meter, and so on.

These classifications also account for particle size. For instance, an ISO 1 cleanroom can contain no more than 2 particles of 0.2 micrometers or smaller per cubic meter. However, if particles larger than 0.2 micrometers are present, the room would no longer meet ISO 1 standards.

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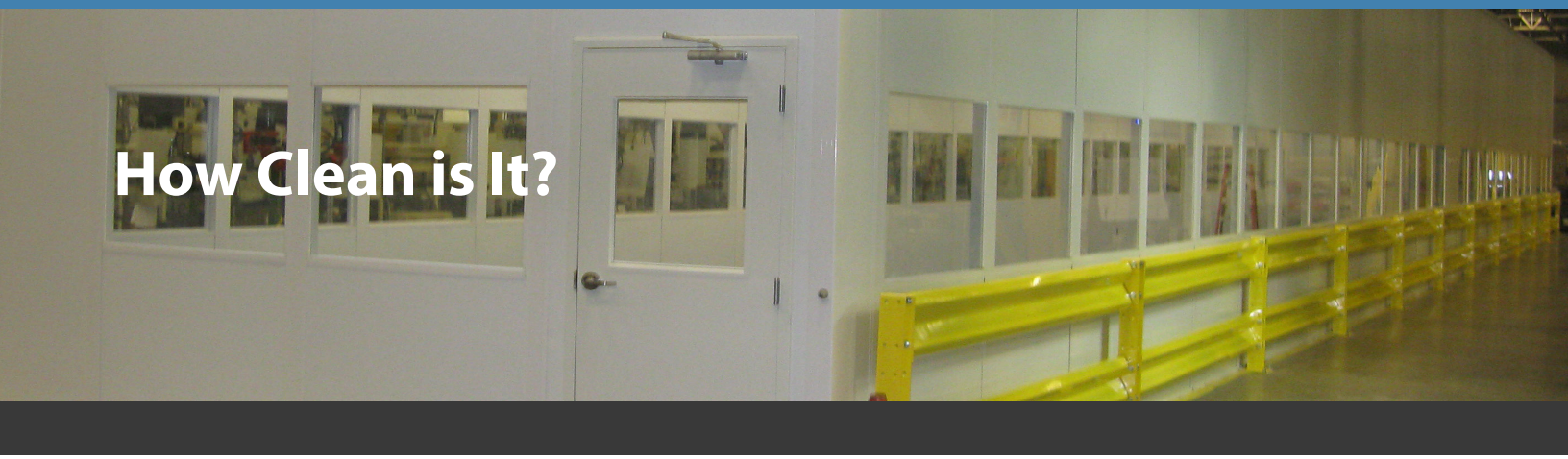

How Clean is It?

To better understand the variance from level to level, let's walk through a couple of examples of what type of cleanroom would be used for a particular application.

ISO 8 / Class 100,000 Cleanroom

This type of cleanroom provides a lower level of contamination control but still surpasses the quality of standard room air. It is commonly used in food and drug product packaging or in the manufacturing of specific devices. Since pharmaceutical packagers must adhere to strict standards for drug containment, a cleanroom environment is often necessary.

ISO 7 / Class 10,000 Cleanroom

This level of cleanroom is commonly found in the medical field. For instance, handling cytotoxic drugs (such as chemotherapy drugs) requires specialized equipment and a controlled environment. A cleanroom environment like Class 10,000/ISO 7 enables technicians to accurately test these drugs in their liquid form to ensure they haven't expired and will maintain their full shelf life.

ISO 6 / Class 1,000 Cleanroom

ISO 6 cleanrooms meet the contamination control standards required in scientific research environments. In such cleanrooms, occupants must wear specialized clothing designed to prevent particles from shedding off their bodies and contaminating the environment. Even the smallest fabric or contaminant can disrupt research, potentially leading to errors that could result in the research being discarded entirely.

ISO 5 / Class 100 Cleanroom (and higher)

ISO 5 cleanrooms and higher are commonly used in high-precision, high-quality manufacturing environments. The production of electronics, for example, demands an extremely clean setting. Workers must fully decontaminate in a gown room before entering the cleanroom. Additionally, strict protocols and decontamination procedures are implemented to maintain the cleanroom's specific ISO classification level.