Cleanroom Technologies Pharma Industries.

An Introduction to Cleanroom Technologies
According to USP797, “a cleanroom can be defined as an environment where the supply, distribution, and filtration of clean air” are appropriately regulated to meet the standards of government authorities.

In general, cleanrooms are important because they help protect manufactured products from contamination. More specifically, cleanroom requirements for pharmaceuticals are meticulously designed for the commercial survival of a successful product.

The importance of a cleanroom in pharma is that they have the ability to control humidity, dust, air pressure, microorganisms, and even the temperature. This helps ensure that the products we get for our health, whether it be over-the-counter or prescribed by your doctor, won’t pose a risk to us.

One of the most well-known aspects of cleanroom requirements for pharmaceuticals is the ISO standard, which determines protocols for air cleanliness, tests, design, operation, and much more.

ISO Classification of Cleanrooms

Within the ISO standards, there are specific instructions for maintaining clean air. It must be so specific that pharmaceutical companies must measure the concentration of air particles and ensure they’re within a given threshold.
Every ISO has a predetermined air concentration threshold depending on the class of the cleanroom. For example, a class 8 cleanroom provides air cleanliness levels of a maximum of 100,000 particles per cubic foot.
Although this may sound complex at first, it’s important to know what class works best for a cleanroom in the pharmaceutical industry. A class 8 cleanroom is only one out of an entire ISO range.

ISO Classification Number	Maximum Concentration Limits (particles/m³ of air) for Particles Equal to and Larger Than the Considered Sizes Shown Below					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1,000	237	102	35	8	
ISO Class 4	10,000	2,370	1,020	352	83	
ISO Class 5	100,000	23,700	10,200	3,520	832	29
ISO Class 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO Class 7				352,000	83,200	2,930
ISO Class 8				3,520,000	832,000	29,300
ISO Class 9				35,200,000	8,320,000	293,000

NOTE: Uncertainties related to the measurement process require that concentration data with no more than three significant figures be used in determining the classification level.

Calculate space pressurization.

An important protocol of cleanrooms is ensuring the right space pressurization.

Maintaining a positive airspace keeps contaminants from infiltrating the room. Although it’s impossible to perfectly maintain this positive space pressure, studies show that a very effective pressure differential would be 0.03 to 0.05 in w.g.
Anything above 0.05 in w.g does not provide “better” contamination control. A fine balance is needed.

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Filtration.

The effective of air filters is determined primarily by particle size, but can be affected by the relative electrical charges of particles and filters. Bacteria typically are quite small, requiring filters that remove particle below 1 micron in size. ANSI/ ASHRAE Standard. Specifies a test procedure for evaluating the performance of air-cleaning devices as function of particle size.

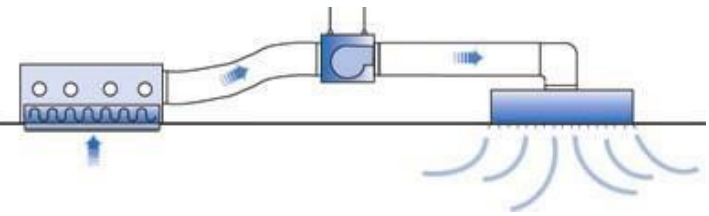
The true HEPA 99.99% filters required only for protective environment rooms.

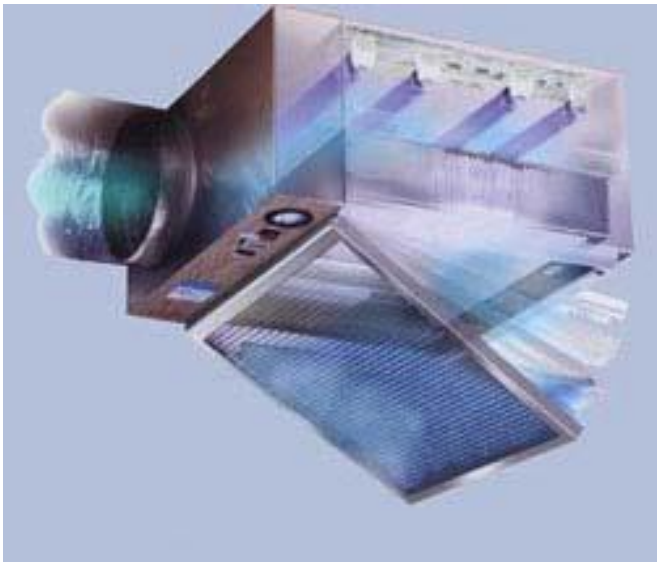
Laminar Array System.

Laminar flow diffusers are nonaspirating diffusers with air flowing downward from the ceiling and minimum entrainment of room air. All laminar diffusers must be room-side accessible for cleaning and/or filter replacement.

The laminar diffusers are set into arrays intended to create uniform laminar airflow profile covering a critical zone

FFU with UV Light
Pre-Filter & HEPA Filter with Side Air inlet Connection





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