Clean Rooms are rooms in which there is an accurate Air Contamination Control and this control is also extended to all equipment, accessories and fittings in this environment.

We will not go into specific details, but will focus only on the airborne contamination.

When it is necessary to prevent contamination from outside the clean room must be over-pressurized (15-20Pa) in relation to the surrounding areas at lower classification.

In general low classified rooms require to be in contact with other classified rooms of higher class (example: class 100 cabinet needs to be in class 10000 or 100000 environment).

Outside microbiology Laboratory
under-pressurized compared with the Lab.

For critical areas interlock buffers and pass-through systems are required to minimize possible contamination during access and goods transfer.

Below a classification table according to the FDA, covering the food sector range.

Clean Area Classification (0.5 µm particles/ft^3)	ISO Designation[b]	> 0.5 mm particles/m^3	Microbiological Active Air Action Levels[c] (cfu/m^3)	Microbiological Settling Plates Action Levels[c,d] (diam. 90mm; cfu/4 hours)
100	5	3,520	1[e]	1[e]
1000	6	35,200	7	3
10,000	7	352,000	10	5
100,000	8	3,520,000	100	50

a. All classifications based on data measured in the vicinity of exposed materials/particles during periods of activity.

b. ISO 14644 -1 designations provide uniform particle concentration values for cleanrooms in multiple industries. An ISO 5 particle concentration is equal to Class 100 and approximately equals EU Grade A.

c. Values represent recommended levels of environmental quality. You may find it appropriate to establish alternate microbiological action levels due to the nature of the operation or method of analysis.

d. The additional use of settling plates is optional.

e. Samples from Class 100 (ISO 5) environments should normally yield no microbiological contaminants.

To guarantee the classification required, not only the efficiency of the filters is important.

It is also essential to consider the proper flow rate that provides a minimum number of air recirculations and the air distribution all over the classified area.

Class 10000 Micro. Lab. in a dairy company.

Interlock buffer between not classified and classified area with shoes and hands washing

The volume to handle in the classified room is larger, and so is the investment.

To reduce costs, if it is not essential to keep the whole volume at the same classification level. It is reasonable to consider the installation of Classified Cabinets* in which the classification is at the highest standard, but due to the volume, although hundreds of air recirculations may be required, the total flow rate is minimal.

At the same time, the surrounding environment can be left at less restricted conditions.

A simple example is a filling unit, protected by a cabinet in a 100000 classified production room.

* See pdf for Classified Cabinets.