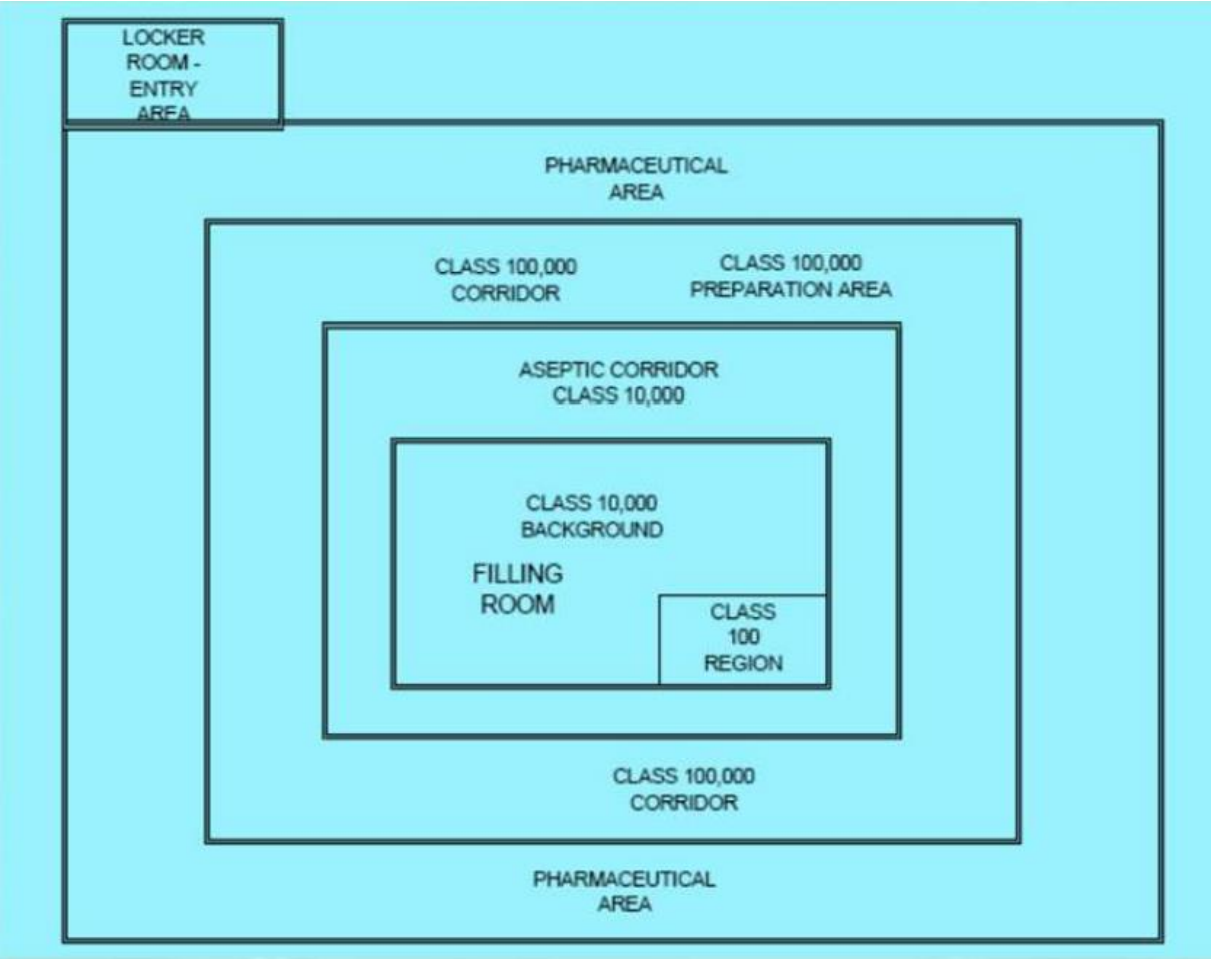
Basic Principles of Safety – Classification Levels Within an Aseptic Facility

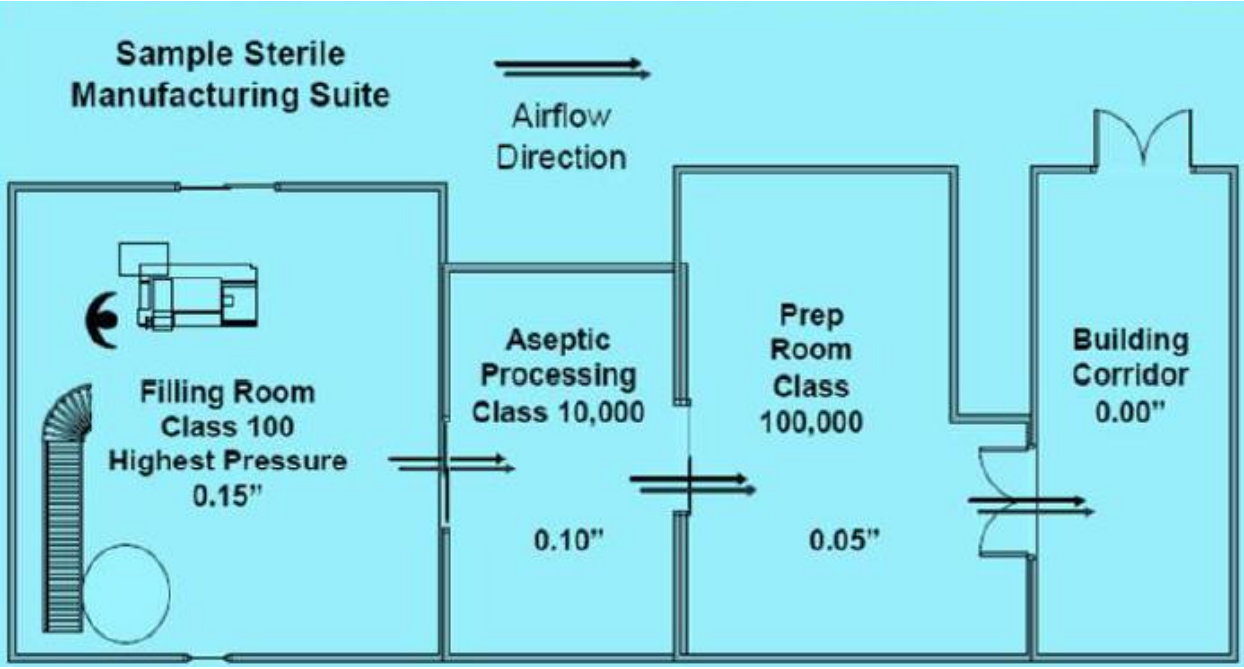
Your Objectives:

At the end of the lesson, you should be able to sequence the levels within an aseptic facility.

Following current building construction prescriptions, an aseptic facility is one that is constructed from uncontrolled, potentially less clean, areas (outer areas) to controlled areas (inner areas), where cleaning is thorough, in such a way that the closer you get to the centre of the premises, the cleaner it is. This strategy is designed to assure that products themselves will not become contaminated.



Pressure cascade:



All rooms are pressurised so as to keep contamination from entering an area and to prevent contamination from moving from one area into another. To pressurise a cleanroom, more air must be put into the room than is removed. That way, when you open a door, air from another area cannot flow into the cleanroom. The most critical or sensitive rooms are surrounded by areas or rooms with lower air pressure.

Cleanroom classifications

Cleanrooms require pre-set limited counts of non-viable (particulates) and viable (bacteria, moulds, fungi, etc.) so as to shield drug products from contamination. In the USA, clean-room classifications range from 1 to 100,000. The classifications are assigned based on the number of particles in the air inside a room. Classifications are based on a concentration of 0.5µm (micrometre) particles per cubic feet of air. For example, in a **class 100** room there would be less than 100 particles of 0.5µm per cubic feet (**ft**^{3}) of air. Typical classifications are **class 10,000** and **class 100,000**. Some areas, like cold-room curtain areas are class 100.

NB: The lower the classification number, the cleaner the room. This also means that when the room classification number is lower, the gowning requirements for that room are more complex and stricter.