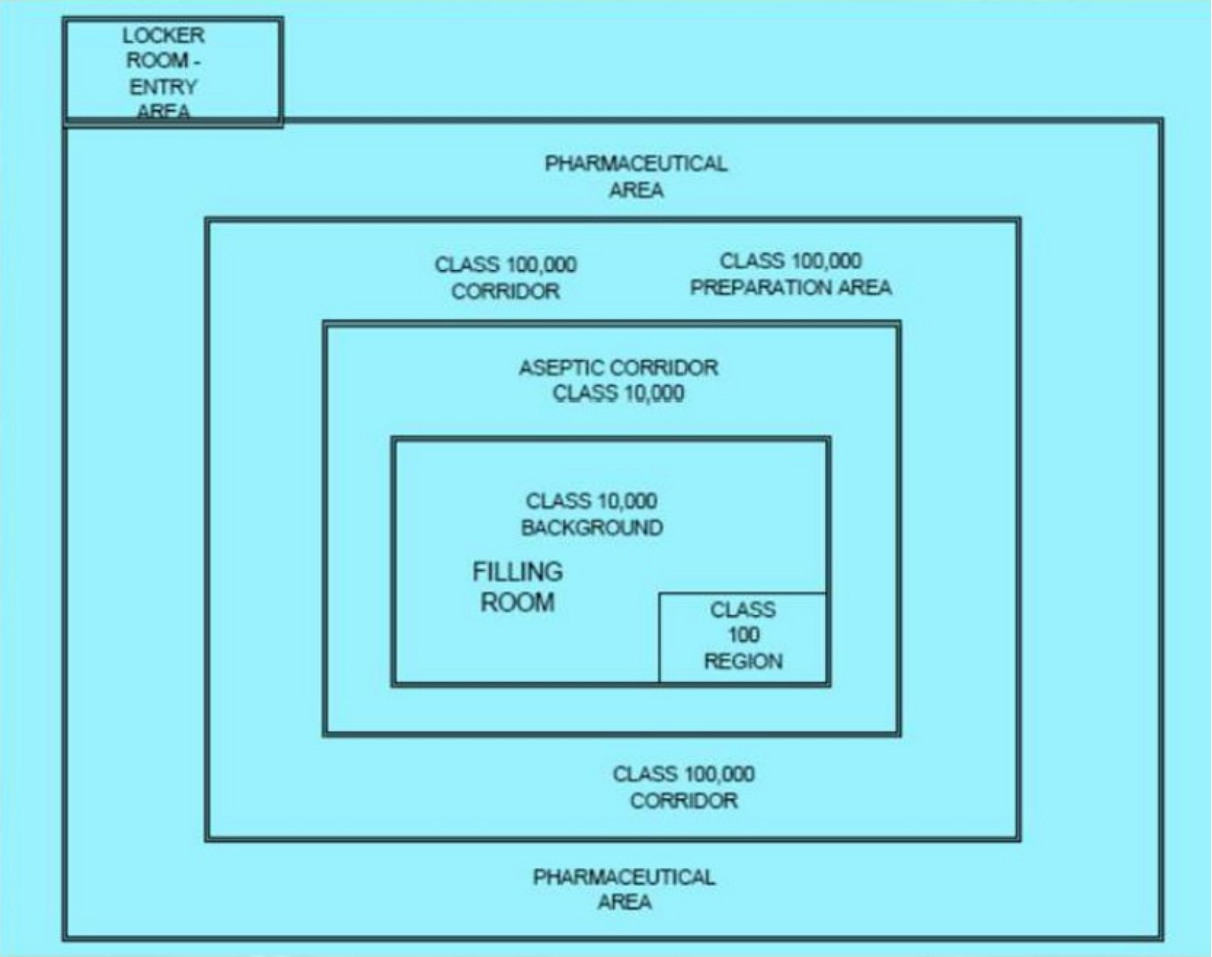
## Basic Principles of Safety – Classification Levels Within an Aseptic Facility

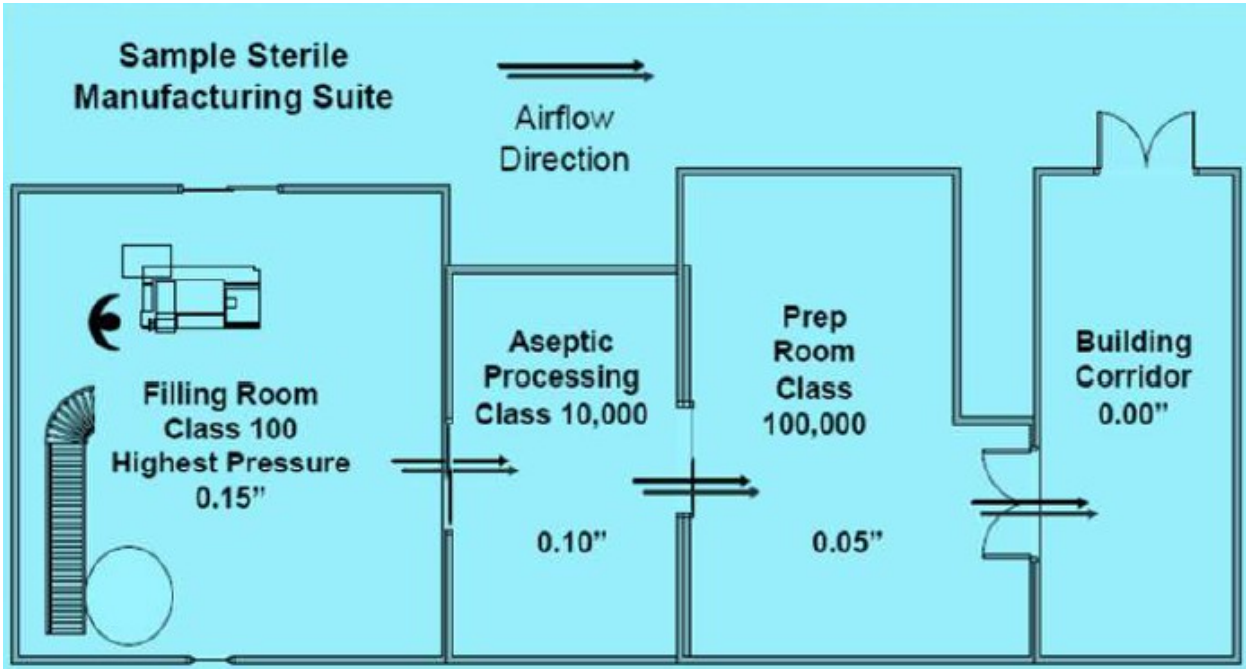
Your Objectives:

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

Following current building construction prescriptions, an _____ facility is one that is constructed from uncontrolled, potentially less clean, areas (outer areas) to controlled _____ (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 _____ themselves will not become _____.


LOCKER ROOM - ENTRY AREA
PHARMACEUTICAL AREA
CLASS 100,000 CORRIDOR
CLASS 100,000 PREPARATION AREA
ASEPTIC CORRIDOR CLASS 10,000
CLASS 10,000 BACKGROUND
FILLING ROOM
CLASS 100 REGION
CLASS 100,000 CORRIDOR
PHARMACEUTICAL AREA

**Pressure cascade:**




All rooms are pressurised so as to keep _____ 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 _____. The most critical or sensitive rooms are surrounded by areas or rooms with lower air _____.

**Cleanroom classifications**

Cleanrooms require pre-set limited counts of non-viable (particulates) and viable (bacteria, moulds, fungi, etc.) so as to shield [ ] products from contamination. In the USA, clean-room [ ] range from 1 to 100,000. The classifications are assigned based on the number of [ ] 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 [ ], 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 [ ].

**Aufgabe Lückentext:**

**Folgende Wörter bitte in den Lückentext einfüllen.**
**Jedes Wort kommt einmal vor.**
**Bitte Gross- und Kleinbuchstaben beachten.**

aseptic, areas, contaminated, contamination, cleanroom, classifications, drug, number, pressure, products, particles, stricter