

Designing of Aseptic Area $\Rightarrow$

Aseptic area is the well defined area where the production of sterile preparation should be carried out & the entry at these area is strictly through the air lock for equipment & Material.

- The Various operations of sterile preparation, filtration, filling, sterilization is carried out under controlled conditions designed to control the presence of any Microbial cell or any air particles. [DEPTH OF BIOLOGY]

- During designing of Aseptic Area focus on Control of Temp., Humidity, air quality control to maintain & to make Aseptic area environment acceptably clean.

The aseptic area is divided in Main 4 grades as per the operations performed inside the area. $\Rightarrow$ [DEPTH OF BIOLOGY]

Grade A $\Rightarrow$ This Zone performed High risk operation

[DEPTH OF BIOLOGY]

Eg $\Rightarrow$ Aseptic filling & Transfer.

Grade B $\Rightarrow$ Background area of Grade A processes.
(Aseptic preparation & filling).

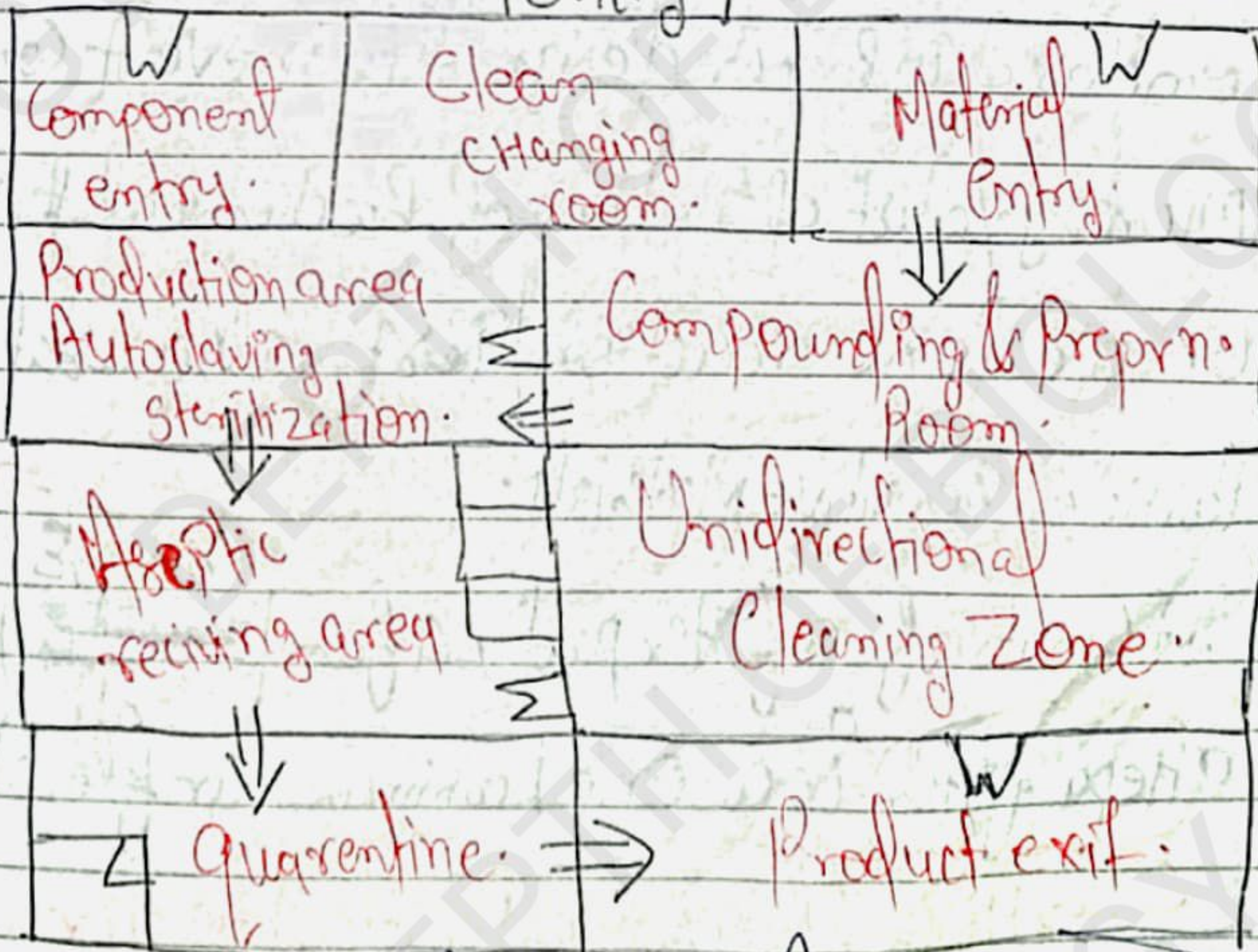
Following factors are considered in designing of
Any Aseptic area $\Rightarrow$

- All aseptic area should as far as possible to avoid entry of Unrelated personnel. [DEPTH OF BIOLOGY]
- In all aseptic areas, all exposed surfaces, walls/roofs should be smooth, unbroken free from any crack to minimize the shedding or deposition of Microbial Cells.
- Doors should be carefully design to avoid any air contamination. Sliding door are not allowed for Aseptic area. Swing door should be open in the flow direction of air or from positive air pressure side to (-ve air pressure side). [DEPTH OF BIOLOGY]

- Pipe & ducts or Other things should be Installed in Such a way that they do not create Unsealed opening & Surfaces that are difficult to clean.
- Changing room should be designed as air Locked.
- Air Locked door should not be open at same time in double door, when 1st door is open, the second door should be close.
- An warning Alarm system should be there to warn in the condition of both doors are open.

[DEPTH OF BIOLOGY]

Entry



[DEPTH OF BIOLOGY]

Layout of Aseptic Area: $\Rightarrow$