

Parenteral Production

Area Planning & Environmental Control in Parenteral Production

- Parenteral products (injectables) must be completely sterile because they are directly introduced into the body.
- Therefore, the production area must be designed very carefully to prevent contamination.

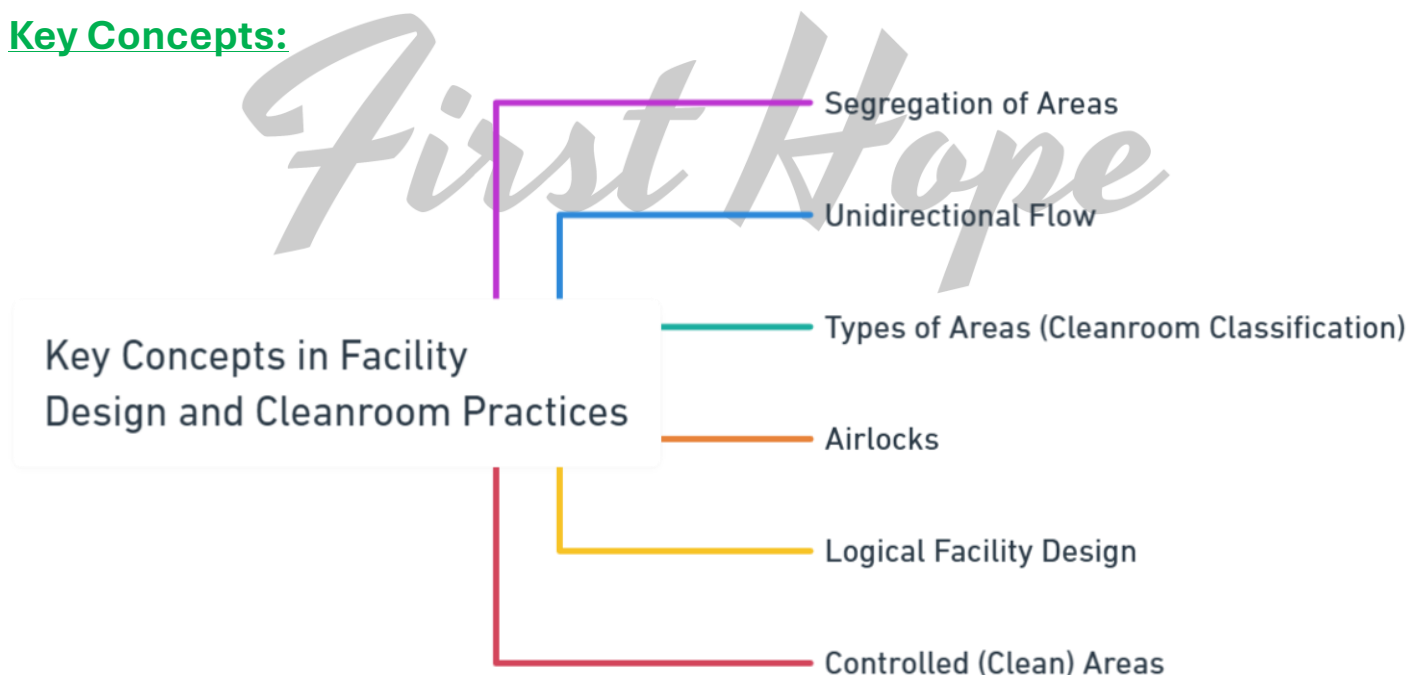
Area Planning (Facility Layout Design)

- Area planning refers to the proper design and arrangement of manufacturing areas to minimize contamination and ensure smooth workflow.

Key Objectives

- Prevent contamination (microbial, particulate, cross-contamination)
- Maintain sterile conditions
- Ensure smooth movement of materials and personnel
- Comply with **GMP (Good Manufacturing Practices)**

Key Concepts:



1. Segregation of Areas

- Different operations are carried out in separate rooms.
- **Example:**
 - Raw material area
 - Preparation area
 - Filling area
 - Sterilization area

- Packaging area

2. Unidirectional Flow

- Movement of materials and personnel should be **in one direction only**
- Prevents cross-contamination and mix-ups
- Avoids backtracking

3. Types of Areas (Cleanroom Classification)

- **Clean areas are classified based on cleanliness levels:**
 - **Grade A:** Critical zone (aseptic filling)
 - **Grade B:** Background area for Grade A
 - **Grade C & D:** Less critical areas (preparation, washing, storage)

4. Airlocks

- Small rooms between two areas of different cleanliness levels.
- Prevent entry of contaminated air.

5. Logical Facility Design

- Separate entry and exit points
- No crossing of clean and dirty materials
- Smooth workflow from raw materials → finished products

6. Controlled (Clean) Areas

- Designed to maintain low levels of particles and microorganisms
- Used for critical sterile operations

Environmental Control

Maintaining controlled conditions inside production areas.

1. Air Quality Control (HVAC System)

- **HEPA filters** remove particles and microorganisms
- **Laminar airflow** provides uniform air movement
- Maintains sterile conditions

2. Air Pressure (Differential Pressure)

- Higher pressure inside clean areas.
- Prevents entry of contaminated air.

3. Temperature Control

- Usually maintained between 18–25°C.

- Ensures product stability and operator comfort.

4. Humidity Control

- **Controlled to:**
 - Prevent microbial growth
 - Avoid static charge
- Important for product quality

5. Air Changes per Hour (ACH)

- Frequent air replacement to maintain cleanliness
- Helps remove contaminants continuously

6. Microbial Control

- **Regular monitoring of:**
 - Air
 - Surfaces
- Use of disinfectants to reduce contamination

7. Particulate Control

- Limits number of particles in air
- Continuous monitoring systems used

Wall and Floor Treatment

- Walls and floors in parenteral production areas must be designed to minimize contamination and allow easy cleaning.

Wall Treatment:

Requirements:

- Smooth surface
- Non-porous
- Free from cracks and joints
- Easy to clean and disinfect

Materials Used:

- Epoxy coating
- PVC panels
- Stainless steel panels

Special Features:

- Rounded corners (coving) between walls and floors
- No sharp edges (prevents dust accumulation)

Floor Treatment:

Requirements:

- Non-slip surface
- Resistant to chemicals and disinfectants
- Smooth and seamless

Materials Used:

- Epoxy flooring
- Vinyl flooring

Important Design:

- Slight slope for drainage
- No gaps or joints

Ceiling Treatment:

- Sealed and smooth
- No cracks or openings
- Light fixtures are flush-mounted

Coving (Corner Treatment)

- Corners are rounded instead of sharp angles
- Prevents accumulation of dirt and microbes
- Easy cleaning

Cleaning and Maintenance

- Regular cleaning schedules
- Use of disinfectants
- Validation of cleaning procedures

Fixtures and Machineries

- Fixtures and machinery used in parenteral production must support sterile operations and prevent contamination.

Fixtures:

1. Pass Boxes

- Used to transfer materials between rooms without contamination.
- May have UV light for sterilization.

2. Laminar Air Flow (LAF) Units

- Provide unidirectional airflow.
- Used in aseptic filling.

3. Air Handling Units (AHU)

- Control air filtration, temperature, and humidity.

Machineries Used:

A. Washing Machines

- Clean containers like vials and ampoules.

B. Sterilizers (Autoclaves)

- Use steam under pressure to sterilize equipment and materials.

C. Dry Heat Sterilizers

- Used for glassware and metal instruments.

D. Filling Machines

- Fill sterile liquid into vials or ampoules under aseptic conditions.

E. Sealing Machines

- Seal containers immediately after filling.

Key Requirements for Equipment:

- Made of stainless steel (non-reactive, easy to clean)
- Easy to dismantle and clean
- Should not generate particles

Change Rooms (Gowning Areas)

- Change rooms are critical areas where personnel prepare before entering clean rooms.

Purpose of Change Rooms

- Prevent entry of contaminants from outside
- Ensure personnel wear sterile garments



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