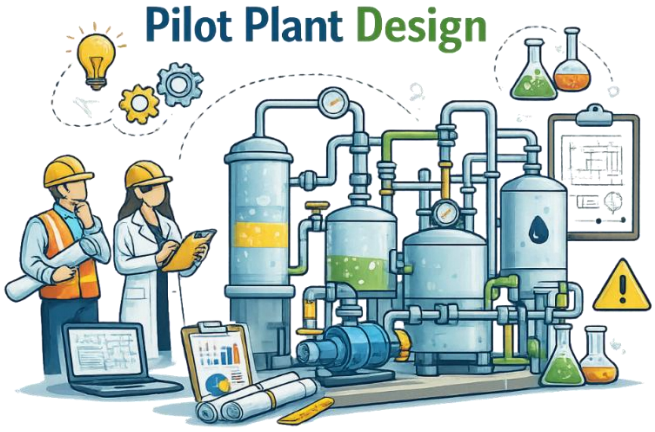
Pilot plant design

Basic Requirements for Pilot Plant Design

- Pilot plant is a small-scale version of a full manufacturing unit.



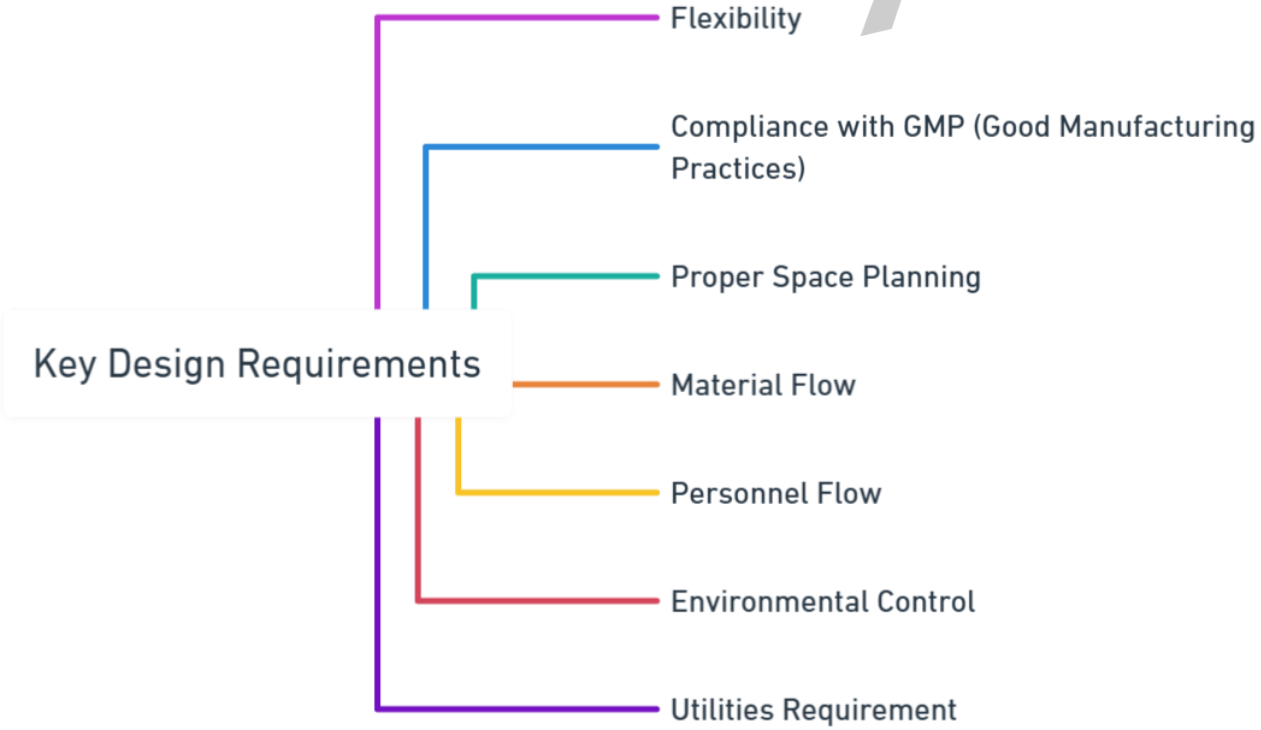
- It is used to test, optimize, and scale up drug production before commercial manufacturing.

Purpose of Pilot Plant

- To convert laboratory-scale formulation into production-scale process
- To identify problems before large-scale manufacturing
- To ensure product quality, safety, and reproducibility

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Key Design Requirements



1. Flexibility

- The pilot plant should be designed to handle different types of dosage forms (tablets, capsules, liquids, etc.)

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- Equipment and layout should allow easy modification
- This is important because formulations often change during development

2. Compliance with GMP (Good Manufacturing Practices)

- Design must follow regulatory guidelines (WHO, FDA, etc.)
- Cleanliness, hygiene, and documentation must be ensured
- Prevent contamination, mix-ups, and errors

3. Proper Space Planning

- **Adequate space for:**
  - Equipment placement
  - Movement of personnel
  - Material handling
- Avoid overcrowding to reduce contamination risk

4. Material Flow

- **Smooth and logical flow of:**
  - Raw materials → processing → finished products
- Should avoid cross-contamination and confusion
- **Separate pathways for:**
  - Raw materials
  - Finished goods
  - Waste

5. Personnel Flow

- Movement of workers should be controlled
- Separate entry and exit points
- Changing rooms (gowning areas) required

6. Environmental Control

- **Control of:**
  - Temperature
  - Humidity
  - Air quality
- Important for product stability and worker safety

7. Utilities Requirement

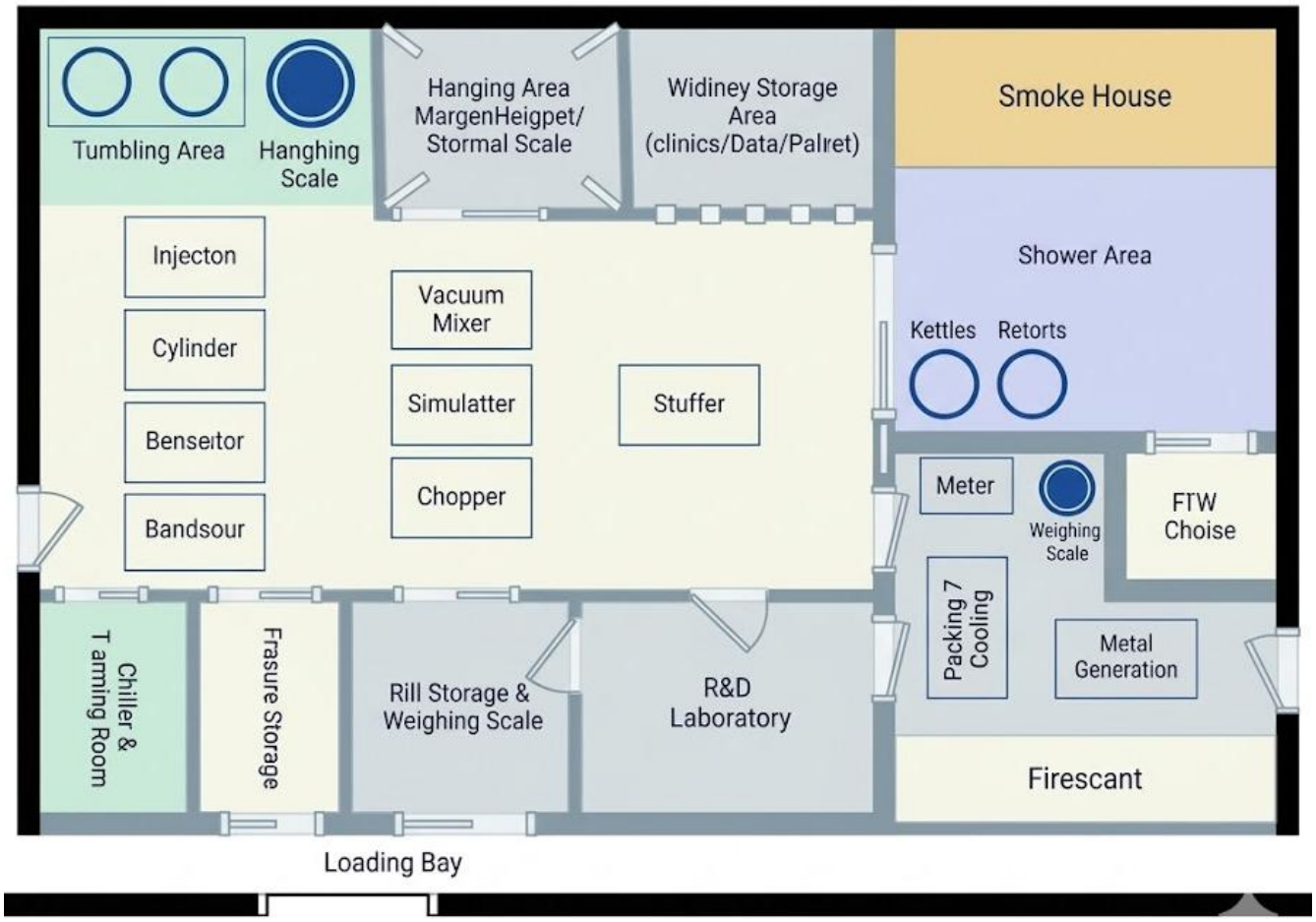
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- **Proper supply of:**
  - Water (purified, distilled)
  - Electricity
  - Compressed air
  - Steam
- Backup systems should be available

Pilot Plant Facility Design

Facility design ensures **smooth workflow, contamination control, safety, and regulatory compliance** in pharmaceutical manufacturing.



1. General Layout Design

- Logical sequence of operations:
  - **Raw material → Processing → Packaging → Storage**
- Proper segregation of different areas to avoid mix-ups and contamination
- Separate areas for different dosage forms

2. Segregation of Areas

- **Different operations should be clearly separated:**

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- Raw material storage area
- Weighing and dispensing area
- Manufacturing/processing area
- Packaging area
- Quality Control (QC) laboratory
- Finished goods storage

➢ This helps prevent cross-contamination and operational confusion.

3. Material and Personnel Flow

➢ Separate entry routes for personnel and materials

➢ Maintain unidirectional flow

➢ Use of pass boxes for safe material transfer

➢ Prevents cross-contamination and ensures smooth movement

4. Clean Rooms

➢ Controlled environments for sensitive products (especially sterile/parenteral)

➢ Classified based on air cleanliness (e.g., **Grade A, B, C, D / ISO classes**)

➢ **Includes:**

- Airlocks
- Gowning rooms

➢ Essential for maintaining sterility

5. Environmental Control (HVAC System)

➢ **Maintains controlled conditions:**

- Temperature
- Humidity
- Air pressure

➢ **Features:**

- **HEPA filters** to remove dust and microorganisms
- **Positive pressure** to prevent entry of contaminants
- Pressure differentials between rooms

6. Storage Areas

➢ **Separate and controlled storage for:**

- Raw materials
- Packaging materials

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- Finished products

➢ **Conditions:**

- Controlled temperature and humidity
- Proper labeling and organization

7. Surfaces and Construction

➢ **Walls, floors, and ceilings should be:**

- Smooth and non-porous
- Easy to clean and disinfect
- Free from cracks and joints
- Resistant to chemicals
- Rounded corners to prevent dust accumulation

8. Lighting

➢ Adequate illumination for safe operations

➢ No shadows or glare

➢ Light fixtures designed to prevent contamination

9. Drainage System

➢ Proper drainage for removal of waste liquids

➢ **Designed to prevent:**

- Backflow
- Contamination

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Equipment Selection in Pilot Plant

- Choosing the right equipment is very important for successful scale-up.

Factors Affecting Equipment Selection

1. Scale of Production

➢ Equipment should match pilot-scale production

➢ Not too small (inefficient) or too large (wasteful)

2. Material Compatibility

➢ Equipment should not react with drug substances

➢ **Usually made of:**

- Stainless steel

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