

Good Manufacturing Practices

(PHAR 533)

Fifth Grade – Spring Semester

Faculty of Pharmacy

Pharmacy Department

Tishk International University



Lecture 6

Buildings and Facilities

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Outlines

- Design and Construction Features
- Important Facilities
- Aseptic processing
- Lighting
- Ventilation
- Sewage and Refuse
- Sanitation
- Maintenance



Learning Outcomes

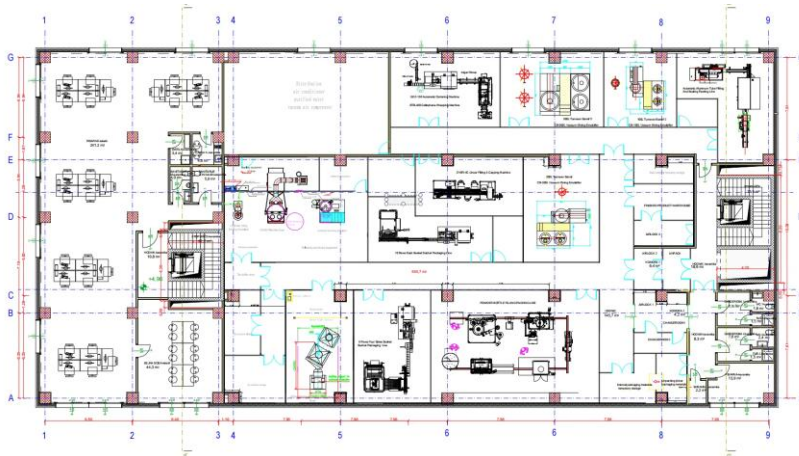
At the end of this chapter, you will be able to:

1. Explain GMP requirements for the design and construction of pharmaceutical buildings, including walls, floors, ceilings, and services.
2. Identify essential facilities and environmental controls.
3. Describe GMP principles for aseptic processing, lighting, and ventilation, including pressure differentials and HEPA filtration.
4. Explain GMP requirements for sanitation, waste disposal, and maintenance.

Design and Construction Features

1- **Walls:** The position of the walls should provide:

- **Orderly movement** of production and waste materials, and personnel.
- Acceptable working conditions by considering **noise levels**.
- Minimize the potential for **cross-contamination** and component **mix-up** during storage and interdepartmental shipping.



Design and Construction Features

2- **Floors:** Floor covering should be selected for:

- **Durability**
- **Cleanability**
- **Resistance** to the chemicals with which it is likely to come into contact

Epoxy flooring provides a durable and readily cleanable surface.



Design and Construction Features

3- Ceilings: Manufacturing areas require a **smooth finish**, often of seamless plaster or gypsum board.

All ceiling fixtures, such as light fittings, air outlets and returns, communication system, and sprinkler heads should be designed to assure ease of **cleaning** and to minimize the potential for **accumulation of dust**.



Design and Construction Features

4- **Services:** provisions must be made for **drains, water, steam, electricity,** and other services to allow for ease of maintenance.

Access should, ideally, be possible without disruption of activity within the actual rooms provided with the services.



Design and Construction Features

- The most efficient and compliant flow pattern is the one that provides for **unidirectional flow**. This methodology minimizes backtracking and thus the potential for cross-contamination and mix-ups during all manufacturing and support (cleaning) operations.
- The **separation** of visitor and employee **entrances** to the manufacturing building should be considered.
- **Visitor entrances** to the manufacturing and support areas should be minimized and restricted to a **single point**.





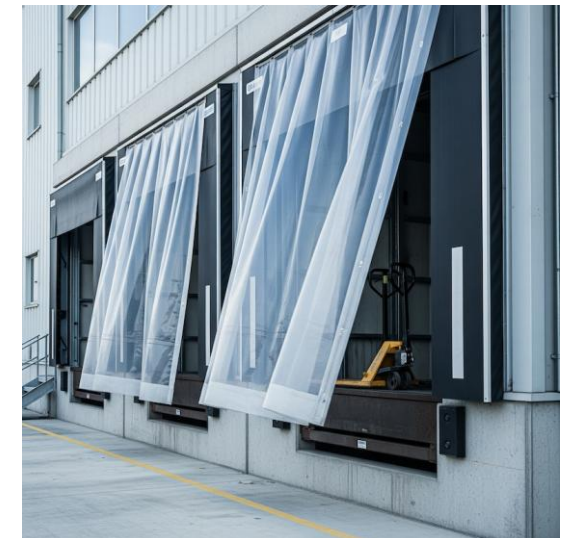
Design and Construction Features

Operations shall be performed within specifically defined areas of adequate size to prevent contamination or mix-ups during the course of the following procedures:

1. **Holding** **rejected** components
2. **Storage** of **released** components, drug product containers, closures
3. **Storage** of **in-process** materials
4. **Manufacturing** and **processing** **operations**
5. **Packaging** and **labeling** **operations**
6. **Control** and **laboratory** **operations**

Design and Construction Features

Receiving areas, where materials are unloaded from delivery transportation, are an **access point** for **airborne contamination**, such as dirt, dust, insects, vermin, birds, and even engine fumes, from the delivery vehicles themselves. Where possible, these **access points** should be protected by flexible curtains to minimize the gap between the truck and the physical facility to the outside when vehicles are unloading.





Important Facilities

1. **Eating and drinking** are permitted only in separate eating facilities.
2. **Smoking** is prohibited in the manufacturing building.
3. **Prominent signs** indicating these rules are posted at entrances to production areas.
4. **Permanent facilities** for breaks.
5. **Hot shower** facilities are provided.
6. **Complete cleaning** with cleansing and disinfectant agents daily. Follow-up inspection by supervisory personnel is logged.
7. **Specific rest areas** for female employees are provided.



Aseptic processing

Aseptic processing, which includes, as appropriate:

1. **Floors, walls, and ceilings** of smooth, hard surfaces that are easily cleanable
2. **Temperature** and **humidity** controls
3. **Air supply filtered** through high-efficiency particulate air (HEPA) filters under positive pressure
4. System for monitoring **environmental conditions**
5. System for cleaning and disinfecting the **room** and **equipment** to produce aseptic conditions
6. System for maintaining any **equipment** used to control the aseptic conditions

Lighting

Normally, a range of **30–50 foot-candles** ensures worker comfort and the ability to perform efficiently and effectively; however, **100 foot-candles** may be needed in some areas, as well as **special lighting** for some operations, such as inspecting filled vials.

Once the light levels have been defined, it is necessary that they be measured periodically and the results recorded.

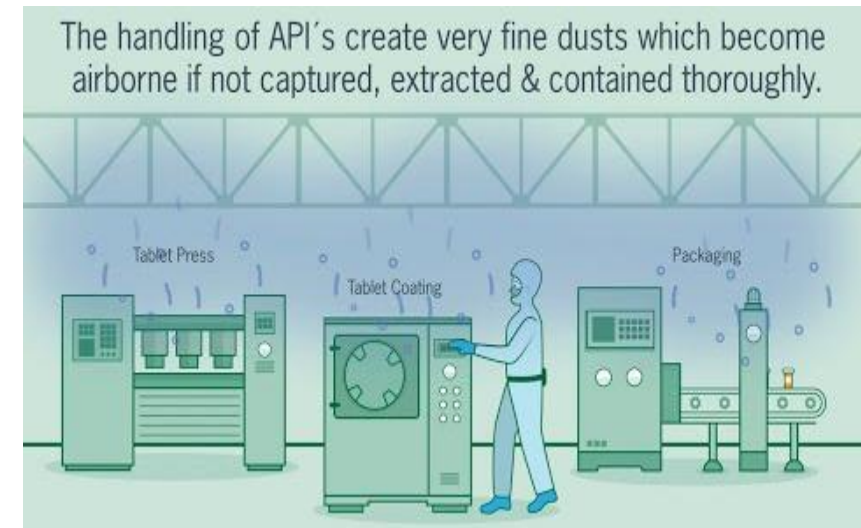


Ventilation

Where **recirculation** of air is acceptable, adequate precautions must be taken to ensure that particulates from a processing area are removed. This will usually require an **alarm system** or an **automatic cutoff** if a **filter develops a hole**.

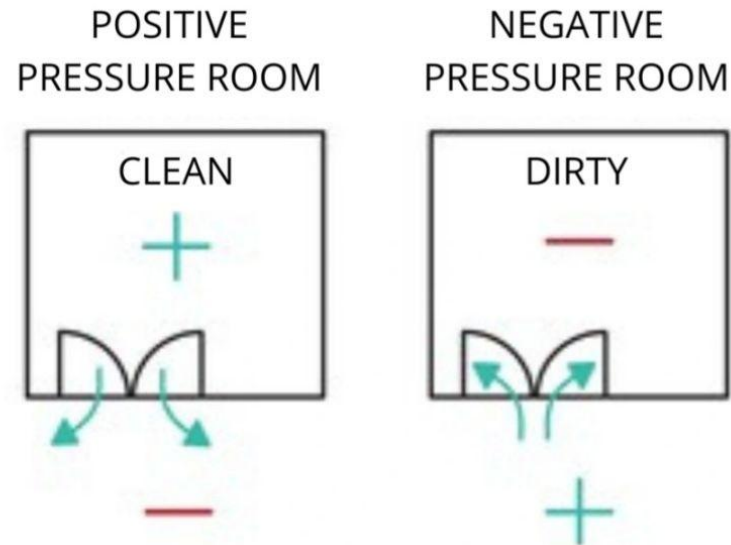
Dust extraction systems should be provided, where appropriate, to minimize this potential problem further.

The **degree of filtration** and the air volumes should be based on the **operations** involved. Specific product manufacturing process requirements are to be addressed in the design.



Ventilation

Solids manufacturing areas are usually maintained at a **negative pressure** in relation to adjacent rooms and corridors to minimize the possibility of dust migration to these other areas.





Sewage and Refuse

A pharmaceutical plant may consider disposal in several different ways:

- 1. Product Disposal:** Any product to be disposed of in an **approved landfill site** should not be left in impermeable glass, plastic, or other containers, which would significantly delay destruction.
- 2. Printed Packaging Disposal:** Such materials should preferably be **incinerated**.
- 3. General Trash and Sewage:** **Containers** used within the plant to accumulate waste materials should be **clearly marked** to denote their designated use.



Sanitation

There shall be **written procedures** assigning responsibility for sanitation and describing in sufficient detail the following:

1. Cleaning schedules
2. Methods
3. Equipment
4. Materials to be used in cleaning the buildings and facilities
5. Cleaning process and frequency

Where appropriate, data should be accumulated to confirm the adequacy of the cleaning procedure.

The use of **rodenticides, fungicides, fumigating agents**, and other techniques should be **combined with good hygienic practices**.

Maintenance

Cracks and holes in walls, floors, or ceilings can provide **access** for insects, rodents, birds, dirt, or microorganisms. They can also **hinder cleaning and sanitation**, thereby increasing the potential for cross-contamination or microbial multiplication.



Floor cracks can also become a **safety hazard** for people or even dislodge materials from trucks.

The ingress of water from **roof leaks** can cause significant **damage to materials and equipment**, give rise to **electrical failures** and **fires**, and result in damage to the basic structure of the building.



Additionally, **holes in the roof** or near the tops of buildings provide ready **access to birds**, which may then be encouraged to nest within the building.

References

Bunn, G. P. (Ed.). (2015). *Good manufacturing practices for pharmaceuticals* (7th ed.). John Wiley & Sons.

