D.PHARM • FIRST YEAR

Pharmaceutics

CHAPTER 6

Pharmaceutical Manufacturing Plants



ENGLISH CHAPTER NOTES

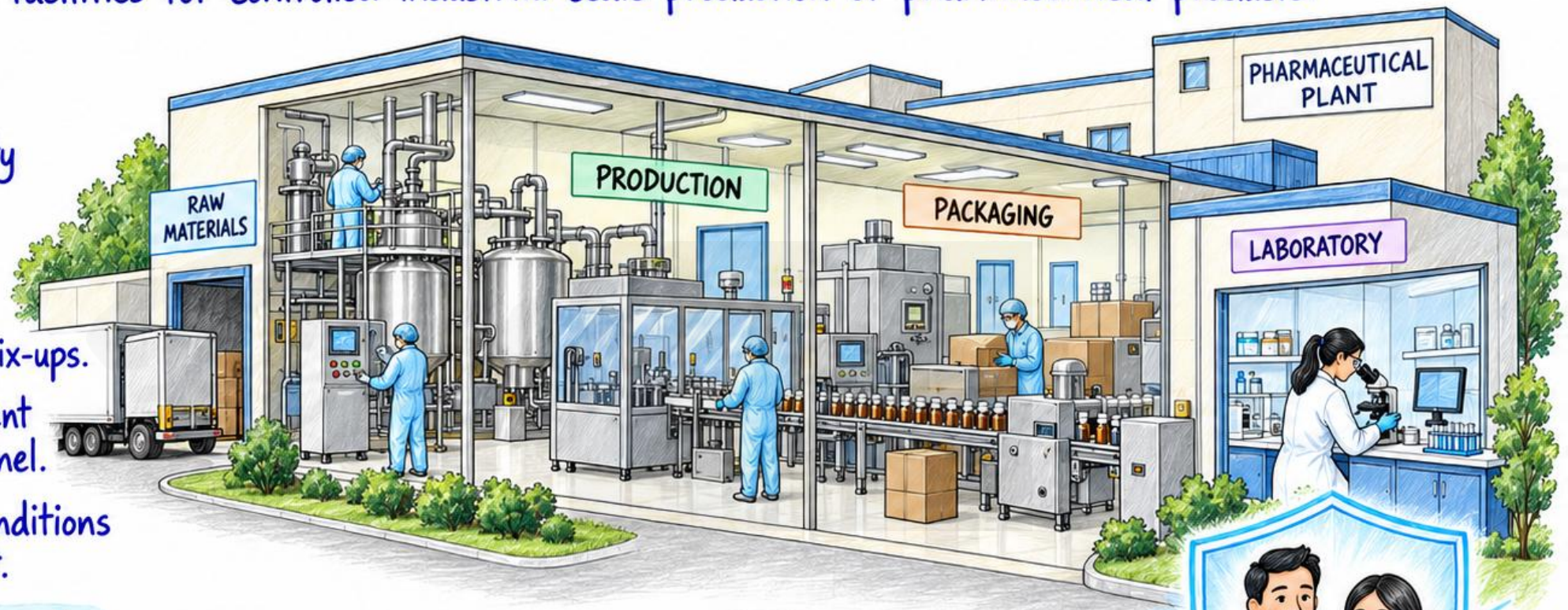
DIPLOMA IN PHARMACY

PHARMACEUTICAL MANUFACTURING PLANTS

Specialized facilities for controlled industrial-scale production of pharmaceutical products.

Main objectives

- Consistent product quality and compliance with applicable GMP.
- Prevent contamination, cross-contamination and mix-ups.
- Support efficient movement of materials and personnel.
- Provide safe working conditions and waste management.



Good design supports

- Cleaning, maintenance and supervision.
- Logical workflow and adequate equipment space.
- Suitable environmental controls.
- Future flexibility without losing process control.



A well-designed building supports quality; it cannot replace controlled procedures and trained people.

TYPES OF MANUFACTURING FACILITIES

Facility requirements depend on the product and its process risks.

1. FORMULATION FACILITIES

- Oral solids: tablets, capsules, powders and granules.
- Liquids: oral or topical solutions and dispersions.
- Semisolids: ointments, creams and gels.
- Sterile products: injections and ophthalmic preparations.



Tablets, capsules, powders and granules



Oral or topical solutions and dispersions



Ointments, creams and gels



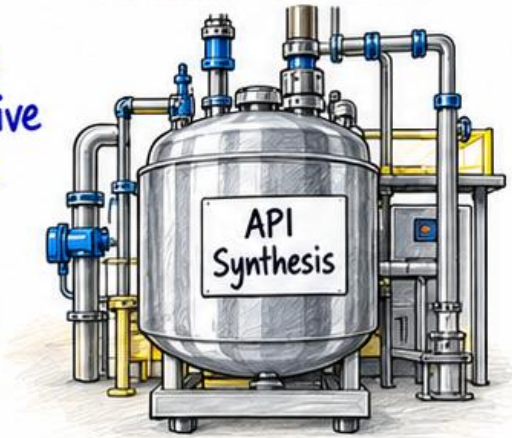
Injections and ophthalmic preparations

2. SPECIALIZED FACILITIES

- Biologics: products made using biological systems.



- API manufacture: production of active drug substances.



3. IMPORTANT DISTINCTION

- Containment and segregation requirements are risk-based.
- Sterile production needs an appropriate sterility-assurance route, not necessarily aseptic filling for every product.
- One layout and environmental standard cannot suit every pharmaceutical facility.

PLANT STRUCTURE AND FINISHES

1. FLOORS AND FOUNDATIONS

- Support the intended equipment loads.
- Suitable smooth, non-shedding, cleanable surfaces.
- Chemical resistance and other properties matched to the area.

2. WALLS AND CEILINGS

- Cleanable surfaces without unnecessary dust-trapping gaps.
- Coved junctions where appropriate.
- Sealed services and suitable lighting.



3. DOORS AND WINDOWS

- Controlled access to production areas.
- Flush observation windows where suitable.
- Airlocks, interlocks or pass-through arrangements where required.

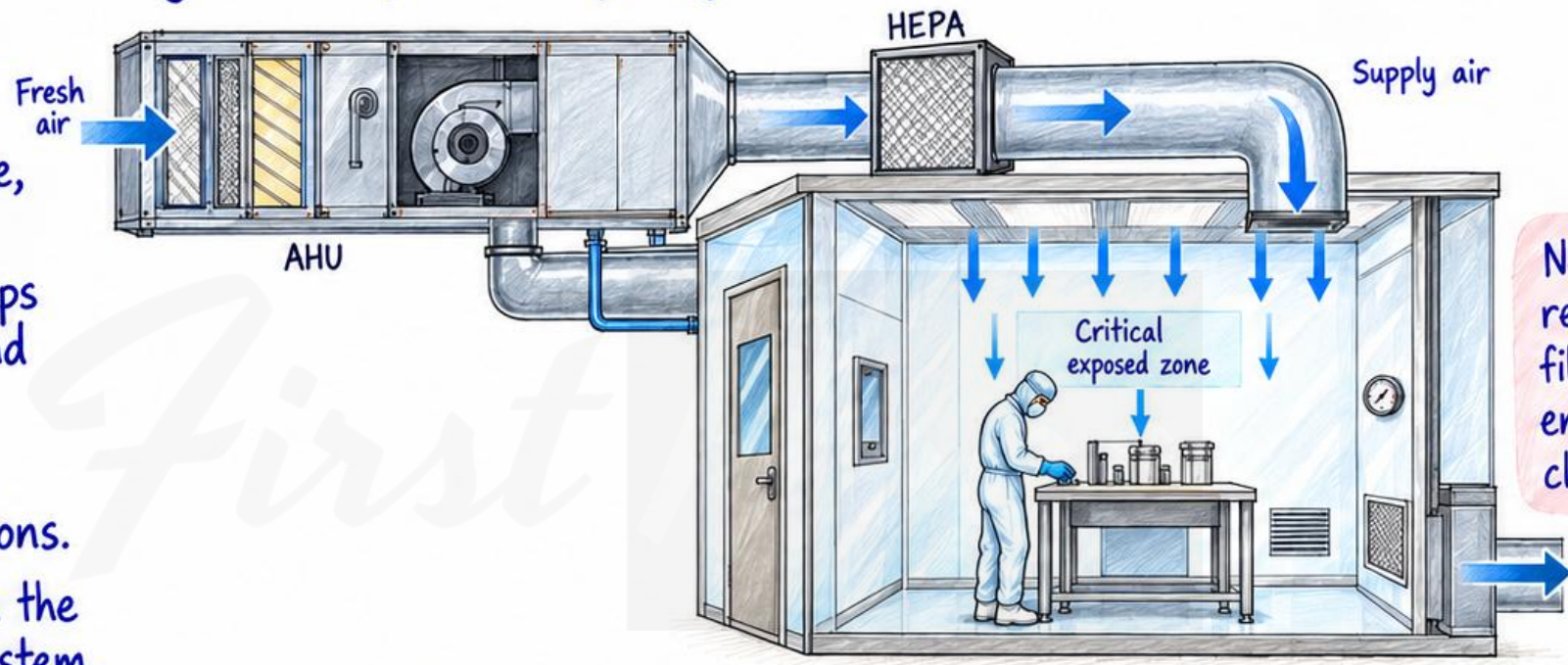
★ Features such as anti-static flooring and airtight doors are selected for relevant risks, not imposed everywhere.

HVAC AND UTILITIES

Utilities can directly affect product quality and must suit their intended use.

HVAC

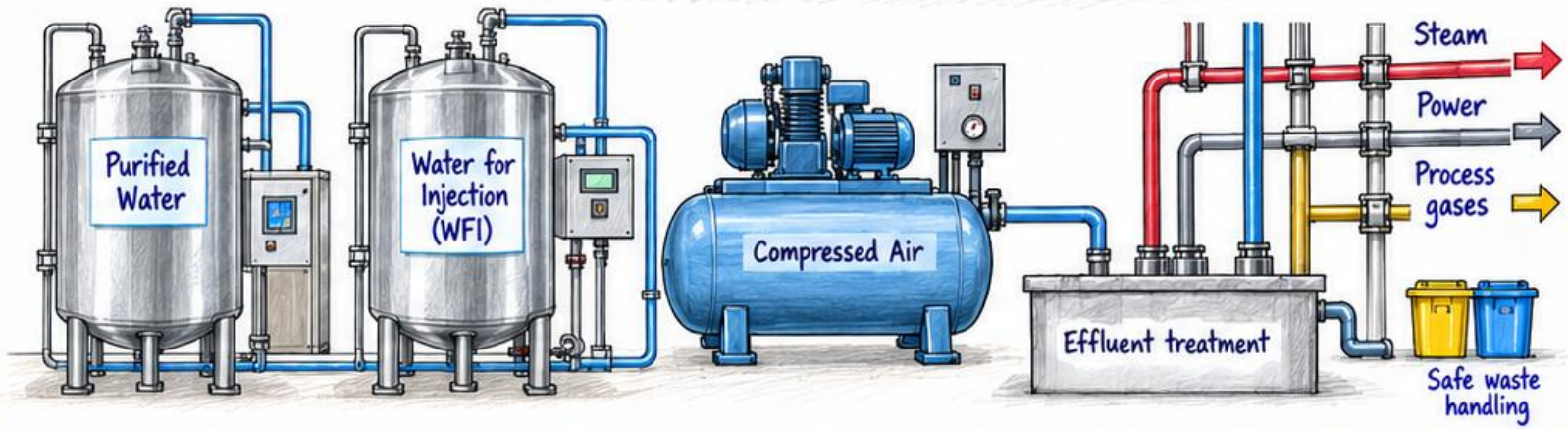
- Controls suitable temperature, humidity and air movement.
- Manages pressure relationships for contamination control and containment.
- HEPA filtration is used in relevant cleanroom applications.
- Cleanroom grades depend on the operation and applicable system.



Not every room requires the same filter, pressure or environmental classification.

Other utilities

- Qualified Purified Water or Water for Injection as required.
- Suitable compressed air and process gases.
- Steam, power and other supporting services.
- Effluent treatment and safe waste handling.



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