# Unit-2

## Pharmaceutical Quality Assurance

### B.Pharma 6th Sem Notes

**Unit: 2**

- **Organization and personnel:** Personnel responsibilities, training, hygiene and personal records
- **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.
- **Equipments and raw materials:** Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials

**Organization and personnel:** Personnel responsibilities, training, hygiene and personal records

# Organization and Personnel

- In a pharmaceutical manufacturing unit, a well-defined organizational structure and trained personnel are essential to ensure product quality, safety, and regulatory compliance.
- Qualified, trained, and hygienic personnel are essential for maintaining product quality and GMP compliance in pharmaceutical manufacturing.

## Personnel Responsibilities

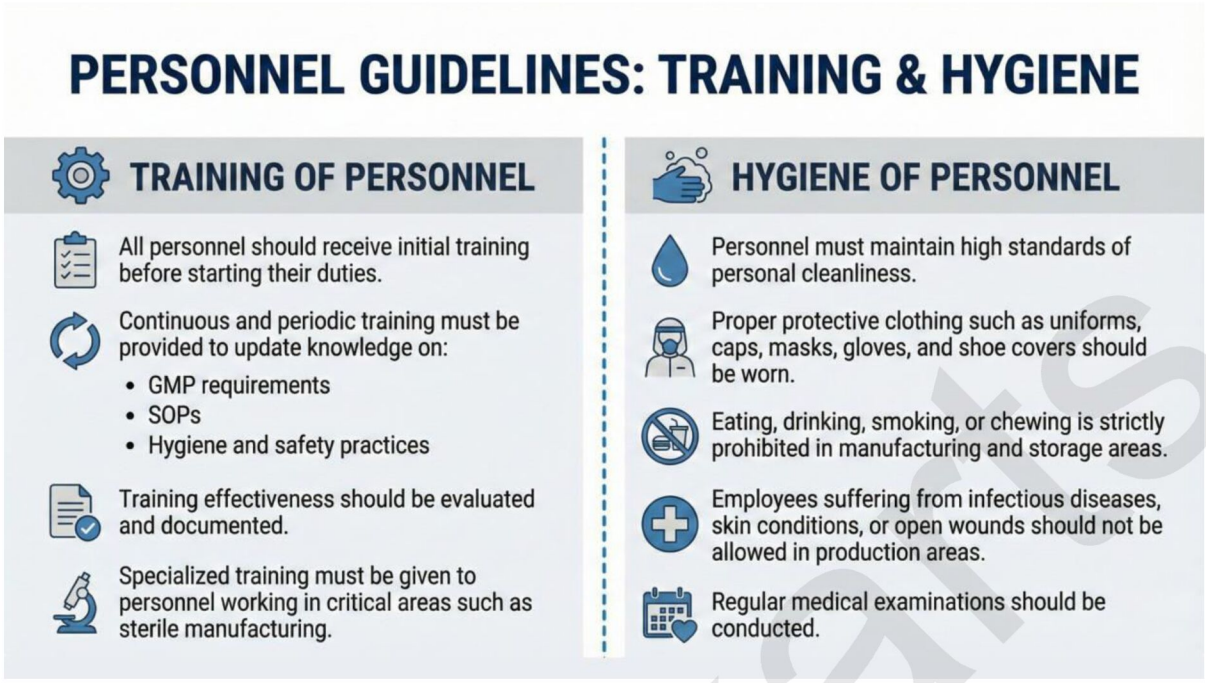
- Each employee must have **clearly defined roles, responsibilities, and authority**.
- Responsibilities should be documented in **job descriptions**.
- Key departments include:
  - **Production Department** – responsible for manufacturing operations.
  - **Quality Control (QC)** – responsible for testing of raw materials, in-process samples, and finished products.
  - **Quality Assurance (QA)** – responsible for overall quality systems, documentation, audits, and batch release.
- The QA department must be **independent** from production and have authority to approve or reject materials and products.
- Personnel must follow **Standard Operating Procedures (SOPs)** and GMP guidelines at all times.

## Training of Personnel

- All personnel should receive **initial training** before starting their duties.
- **Continuous and periodic training** must be provided to update knowledge on:
  - GMP requirements
  - SOPs
  - Hygiene and safety practices
- Training effectiveness should be **evaluated and documented**.
- Specialized training must be given to personnel working in **critical areas** such as sterile manufacturing.

## Hygiene of Personnel

- Personnel must maintain **high standards of personal cleanliness**.
- Proper **protective clothing** such as uniforms, caps, masks, gloves, and shoe covers should be worn.
- Eating, drinking, smoking, or chewing is **strictly prohibited** in manufacturing and storage areas.
- Employees suffering from **infectious diseases, skin conditions, or open wounds** should not be allowed in production areas.
- Regular **medical examinations** should be conducted.




## Personal Records

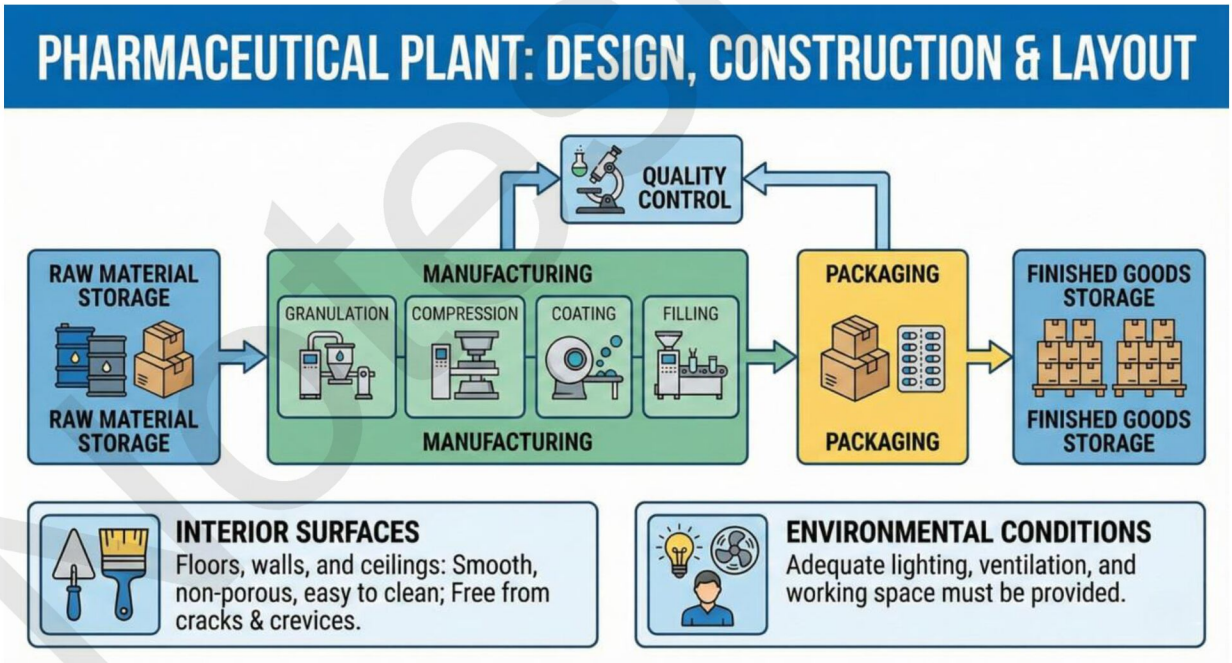
- Complete and accurate **personnel records** must be maintained, including:
  - Personal details
  - Educational qualifications
  - Work experience
  - Training records
  - Medical examination reports
- Records should be **up-to-date, confidential, and readily available** for inspection.
- Documentation helps ensure **traceability and regulatory compliance**.

# Premises

Pharmaceutical premises must be designed, constructed, and maintained in a manner that ensures product quality, prevents contamination, and complies with GMP requirements.

## Design, Construction, and Plant Layout

- Premises should be **designed to suit the type of pharmaceutical products** being manufactured.
- The layout must ensure a **logical flow of materials, personnel, and processes** to avoid mix-ups and cross-contamination.
- Separate areas should be provided for:
  - Raw material storage
  - Manufacturing
  - Quality control
  - Packaging
  - Finished goods storage
- Floors, walls, and ceilings should be:
  - Smooth, non-porous, and easy to clean
  - Free from cracks and crevices
- Adequate **lighting, ventilation, and working space** must be provided.




## Maintenance of Premises

- Premises must be kept in a **good state of repair** at all times.
- Regular **preventive maintenance programs** should be implemented.
- Any damage to walls, floors, or ceilings must be **repaired immediately**.
- Maintenance activities should not pose a risk of contamination to products.
- Maintenance records must be **properly documented**.

## Sanitation

- A high level of **cleanliness and hygiene** must be maintained in all areas.
- Written **cleaning and sanitation SOPs** should be followed.
- Cleaning schedules must specify:
  - Area to be cleaned
  - Cleaning method
  - Cleaning agents used
  - Frequency
- Waste materials should be **removed regularly**.
- Pest control programs should be in place to prevent infestation.

## Environmental Control

- Environmental conditions such as:
  - Temperature
  - Humidity
  - Air quality

  must be **controlled and monitored**.
- HVAC systems should maintain suitable conditions for manufacturing and storage.
- Environmental monitoring records must be maintained.
- Special controls are required in areas handling **sensitive or sterile products**.

## Utilities and Maintenance of Sterile Areas

- Utilities such as:
  - Water (Purified Water / WFI)
  - Steam
  - Compressed air
  - Gases

  must be of **appropriate quality**.
- Sterile areas must have:
  - Controlled air pressure (positive pressure)
  - HEPA-filtered air
  - Controlled temperature and humidity
- Entry into sterile areas should be restricted and controlled.
- Regular **validation and qualification** of utilities and sterile areas is mandatory.

## Control of Contamination

- Measures must be taken to prevent:
  - Cross-contamination
  - Microbial contamination
  - Particulate contamination
- Use of **segregated areas** and **dedicated equipment** where required.
- Proper gowning procedures must be followed.
- Movement of personnel and materials should be **controlled and documented**.

- Cleaning, disinfection, and environmental monitoring play a key role in contamination control.

# Equipment and Raw Materials

Proper selection, qualification, and maintenance of equipment and effective control of raw materials are essential to ensure consistent product quality and GMP compliance.

## Equipment Selection

- Equipment should be **suitable for its intended purpose** and capable of producing products of the required quality.
- It should be designed to:
  - Prevent contamination and cross-contamination
  - Allow easy cleaning and maintenance
  - Minimize operator error
- Equipment coming in contact with products should be made of **non-reactive, non-toxic, and corrosion-resistant materials** (e.g., stainless steel).
- Equipment capacity and performance should match the **scale of production**.

## Purchase Specifications of Equipment

- Equipment should be purchased based on **written and approved specifications**.
- Purchase specifications should include:
  - Equipment name and purpose
  - Design and construction materials
  - Capacity and performance requirements
  - Accuracy and calibration requirements
  - Safety features
  - Compliance with GMP standards
- Supplier qualification and technical documentation must be verified before purchase.

## Maintenance of Equipment

- All equipment must be **properly installed, qualified, and validated** where required.
- A **preventive maintenance program** should be established.
- Equipment must be:
  - Regularly cleaned
  - Calibrated at defined intervals
  - Checked for proper functioning
- Equipment breakdowns should be documented and investigated.
- Maintenance and calibration records must be **maintained and reviewed**.

## Purchase Specifications of Raw Materials

- Raw materials should be purchased only from **approved and qualified suppliers**.
- Written specifications should be available for each raw material, including:
  - Name and description

  - Identification tests
  - Purity and quality standards
  - Storage conditions
  - Shelf life or retest period
- Each raw material should be accompanied by a **Certificate of Analysis (CoA)**.
- Incoming materials must be **quarantined** until approved by Quality Control.

### Stores for Raw Materials and Their Maintenance

- Raw materials must be stored in **designated, clean, and well-organized storage areas**.
- Storage conditions such as **temperature, humidity, and light** should be controlled as required.
- Materials should be:
  - Properly labeled (name, batch number, status)
  - Segregated as approved, rejected, or under quarantine
- FIFO (First In, First Out) or FEFO (First Expiry, First Out) systems should be followed.
- Storage areas should be regularly cleaned and inspected.
- Pest control measures must be implemented.
- Storage and issue records must be **accurate and up-to-date**.

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