WELCOME

TO

This is an Education Platform

We Provide PDF Notes for Pharmacy Students

Web Site http://www.fdspharmacy.in/

You tube https://www.youtube.com/c/FDSpharmacy

Telegram https://t.me/Fdspharmacy

App https://play.google.com/store/apps/details?id=com.FDSPharmacyMedia.FDSPharmacy

E-mail fdspharmacyinfo@gmail.com

PHARMACEUTICAL QUALITY ASSURANCE

UNIT 2

TOPIC :

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

Organization & Personnel In Pharmaceutical Industry

→ The pharmaceutical industry requires a well-structured organization and qualified personnel to ensure the production of safe, effective, and high-quality medicines. Proper organization helps in smooth functioning of manufacturing, quality control, research, marketing, and administrative activities. Personnel are responsible for carrying out various operations according to Good Manufacturing Practices (GMP) and regulatory requirements.

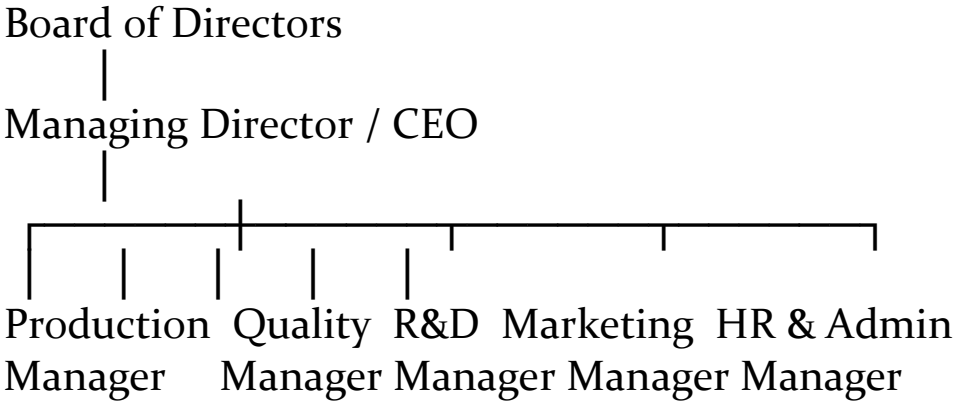
Organization of Pharmaceutical Industry

- Organization refers to the systematic arrangement of different departments and personnel to achieve the objectives of the pharmaceutical company.

Objectives of Organization

- Ensure smooth manufacturing operations.
- Maintain product quality and safety.
- Achieve regulatory compliance.
- Improve productivity and efficiency.
- Promote research and development.
- Ensure proper distribution and marketing of medicines.

Organization Chart



1. Board of Directors

→ The Board of Directors is the highest authority in a pharmaceutical company.

Responsibilities

- Formulate company policies.
- Set long-term goals and objectives.
- Approve budgets and investments.
- Monitor overall performance of the company.
- Ensure legal and ethical compliance.

2. Managing Director (Md) / Chief Executive Officer (Ceo)

→ The Managing Director or CEO manages the overall operations of the company.

Responsibilities

- Implement company policies.
- Coordinate all departments.
- Take strategic business decisions.
- Ensure profitability and growth.
- Represent the company before regulatory authorities and stakeholders.

Production Department

- The production department is responsible for manufacturing pharmaceutical products according to approved procedures and GMP guidelines.

Production Manager

Responsibilities

- Plan and supervise manufacturing activities.
- Ensure production targets are achieved.
- Maintain GMP compliance.
- Ensure proper utilization of manpower and equipment.
- Coordinate with quality and maintenance departments.

Under Production Manager

Production Supervisors

- Monitor daily manufacturing operations.
- Supervise workers and technicians.
- Ensure adherence to SOPs.
- Maintain production records.

Production Pharmacists

- Participate in formulation and manufacturing.
- Ensure correct use of raw materials.
- Monitor production processes.
- Maintain batch manufacturing records.

Operators and Technicians

- Operate production equipment.
- Perform cleaning and maintenance.
- Assist in manufacturing tablets, capsules, injections, syrups, and other dosage forms.

Quality Department

→ The quality department ensures that pharmaceutical products meet required quality standards.

Quality Manager

Responsibilities

- Ensure product quality and safety.
- Maintain compliance with GMP and regulatory requirements.
- Coordinate quality control and quality assurance activities.

Quality Control (QC)

→ Quality Control is concerned with testing and analysis of materials and products.

QC Head

Responsibilities

- Test raw materials.
- Test in-process samples.
- Test finished products.
- Approve or reject materials.
- Maintain laboratory records.
- Prepare analytical reports.

Functions of QC

- Sampling.
- Testing.
- Validation of analytical methods.
- Stability studies.
- Environmental monitoring.

Quality Assurance (QA)

→ Quality Assurance ensures that products are consistently produced according to quality standards.

QA Head

Responsibilities

- Implement GMP guidelines.
- Review manufacturing records.
- Conduct internal audits.
- Handle deviations and change controls.
- Approve product release.
- Manage documentation systems.

Functions of QA

- Documentation control.
- Validation activities.
- Self-inspection.
- Vendor qualification.
- Product quality review.

Research and Development (R&D) Department

→ The R&D department is responsible for developing new pharmaceutical products and improving existing formulations.

R&D Manager

Responsibilities

- Plan research activities.
- Develop new products.
- Improve existing formulations.
- Conduct technology transfer.

Research Scientists

Responsibilities

- Discover new drug molecules.
- Study drug safety and efficacy.
- Conduct stability studies.
- Develop analytical methods.

Formulation Scientists

Responsibilities

- Develop dosage forms.
- Improve bioavailability.
- Enhance stability of products.
- Optimize manufacturing processes.

Marketing Department

→ The marketing department promotes pharmaceutical products and increases sales.

Marketing Manager

Responsibilities

- Develop marketing strategies.
- Plan promotional activities.
- Analyze market trends.
- Manage product positioning.

Medical Representatives (MRs)

Responsibilities

- Visit doctors and hospitals.
- Provide scientific information.
- Distribute product samples.
- Promote pharmaceutical products.

Sales Executives

Responsibilities

- Manage product sales.
- Coordinate with distributors.
- Achieve sales targets.
- Maintain market presence.

Human Resource (HR) and Administration Department

→ This department manages employees and administrative activities.

Responsibilities

Human Resource

- Recruitment and selection.
- Employee training.
- Performance evaluation.
- Employee welfare programs.

Administration

- Office management.
- Record maintenance.
- Security arrangements.
- Facility management.

Personnel

➢ Personnel refers to all employees working in various departments of a pharmaceutical organization.

Importance of Personnel

- Manufacture quality medicines.
- Ensure compliance with GMP.
- Maintain productivity.
- Prevent errors and contamination.
- Support company growth.

Key Personnel

→ Key personnel are individuals holding critical positions responsible for product quality, safety, and regulatory compliance.

Head of Production

Responsibilities

- Supervise manufacturing activities.
- Ensure compliance with approved procedures.
- Maintain production records.
- Implement GMP requirements.
- Train production personnel.

Head of Quality Control

Responsibilities

- Approve testing procedures.
- Monitor laboratory operations.
- Review analytical results.
- Ensure quality standards are met.
- Maintain laboratory documentation.

Head of Quality Assurance

Responsibilities

- Ensure GMP implementation.
- Review batch records.
- Conduct audits.
- Approve product release.
- Maintain quality management system.

Authorized Person

→ An Authorized Person is a qualified individual approved by regulatory authorities to release pharmaceutical products.

Responsibilities

- Review manufacturing records.
- Review quality control reports.
- Verify GMP compliance.
- Authorize release of finished products.
- Ensure products meet regulatory requirements.

Responsibilities of Personnel

➢ Every employee has specific responsibilities to ensure product quality and safety.

General Responsibilities

- Follow GMP guidelines.
- Work according to SOPs.
- Maintain cleanliness and hygiene.
- Report deviations immediately.
- Prevent contamination.
- Handle equipment properly.
- Maintain accurate records.
- Follow safety procedures.

Personnel Training

→ Training ensures employees are competent and capable of performing their duties effectively.

Objectives of Training

- Improve knowledge and skills.
- Ensure GMP compliance.
- Enhance safety awareness.
- Reduce errors and deviations.

Types of Training

1. Induction Training

- Given to new employees before starting work.

2. GMP Training

- Provides knowledge of Good Manufacturing Practices.

3. SOP Training

- Teaches standard operating procedures.

4. Safety Training

- Covers workplace safety and emergency procedures.

5. Refresher Training

- Conducted periodically to update knowledge.

6. Specialized Training

- Required for sterile areas, laboratories, and specialized operations.

Training Records

- Training date.
- Topic covered.
- Trainer details.
- Employee attendance.
- Evaluation results.

Personnel Hygiene

→ Good personal hygiene is essential to prevent contamination of pharmaceutical products.

Hygiene Requirements

Personal Cleanliness

- Bathe regularly.
- Keep nails clean and trimmed.
- Maintain good personal health.

Protective Clothing

Personnel must wear:

- Clean uniforms.
- Head covers.
- Face masks.
- Gloves.
- Shoe covers.

Hand Hygiene

- Wash hands before entering production areas.
- Use approved sanitizers.
- Follow hand-washing procedures.

Prohibited Activities

- Eating in production areas.
- Drinking in manufacturing zones.
- Smoking.
- Chewing gum.
- Wearing jewelry.
- Using cosmetics and perfumes.

Health Monitoring

Personnel with:

- Infectious diseases.
- Skin infections.
- Open wounds.
- Respiratory illnesses.

should not enter manufacturing areas until medically cleared.

Personnel Records

- Personnel records are maintained to ensure accountability, traceability, and regulatory compliance.

Types of Personnel Records

Qualification Records

- Educational qualifications.
- Professional certifications.

Employment Records

- Job designation.
- Department.
- Experience details.

Training Records

- Training programs attended.
- Assessment results.

Health Records

- Medical examinations.
- Fitness certificates.

Attendance Records

- Attendance details.
- Shift schedules.
- Leave records.

Importance of Personnel Records

- Demonstrate regulatory compliance.
- Facilitate inspections and audits.
- Monitor employee performance.
- Maintain employee history.
- Ensure proper training documentation.
- Improve workforce management.