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 1

TOPIC :

- **Quality Assurance and Quality Management concepts :** Definition and concept of Quality control, Quality assurance and GMP

Quality Management System (QMS)

→ Quality Management System (QMS) is a structured system of policies, procedures, processes, and resources used to ensure that pharmaceutical products consistently meet quality standards and regulatory requirements.

→ According to ISO, QMS is a management system that directs and controls an organization with regard to quality.

→ In the pharmaceutical industry, QMS ensures that medicines are safe, effective, pure, and of consistent quality throughout their shelf life.

Objectives of QMS

1. Ensure consistent product quality.
2. Meet customer and regulatory requirements.
3. Improve customer satisfaction.
4. Prevent defects and quality failures.
5. Promote continuous improvement.
6. Maintain product safety and efficacy.
7. Reduce operational risks and costs.

Components of QMS

1. Management Responsibility

- Establish quality policy and objectives.
- Allocate resources.
- Review quality performance regularly.

2. Resource Management

- Qualified personnel.
- Proper facilities and equipment.
- Training programs.

3. Product Realization

- Procurement of raw materials.
- Manufacturing processes.
- Packaging and distribution.

4. Measurement, Analysis and Improvement

- Audits and inspections.
- Corrective and preventive actions (CAPA).

- Continuous quality improvement.

Importance of QMS

- Ensures product safety and effectiveness.
- Improves customer confidence.
- Helps comply with GMP and regulatory guidelines.
- Reduces wastage and production errors.
- Enhances company reputation.
- Improves productivity and efficiency.

Concept of Quality

→ According to USFDA:
→ "Quality is the ability of a product or service to satisfy stated or implied customer needs."
→ Quality is not only freedom from defects but also fitness for intended use.
→ In pharmaceuticals, quality means that a drug product is:
  - Safe
  - Effective
  - Pure
  - Stable
  - Consistent

Characteristics of Quality

1. Safety
2. Effectiveness
3. Purity
4. Stability
5. Reliability
6. Consistency
7. Compliance with standards

Importance of Quality

- Protects patient health.
- Ensures therapeutic effectiveness.
- Maintains consistency among batches.
- Increases customer satisfaction.

- Supports regulatory compliance.
- Enhances market acceptance.

Quality Assurance (QA)

→ Quality Assurance (QA) is the sum of all planned and systematic activities necessary to ensure that pharmaceutical products consistently meet established quality standards.
→ QA focuses on preventing defects rather than detecting them.

Objectives of Quality Assurance

1. Ensure product quality.
2. Maintain batch-to-batch consistency.
3. Prevent errors and contamination.
4. Follow GMP guidelines.
5. Ensure patient safety.
6. Improve manufacturing processes.

Scope of Quality Assurance

QA covers all activities from product development to distribution:

- Raw material procurement
- Manufacturing
- In-process controls
- Quality Control
- Packaging
- Storage
- Distribution
- Documentation
- Validation

Elements of Quality Assurance

1. Good Manufacturing Practices (GMP)

- Ensures products are manufactured under controlled conditions.

2. Documentation

- Maintains records of all manufacturing and testing activities.

3. Quality Control

- Testing and evaluation of materials and products.

4. Validation

- Proof that equipment and processes perform consistently.

5. Training

- Training of employees regarding SOPs and GMP.

6. Self-Inspection and Audits

- Regular review of quality systems.

7. CAPA

- Corrective and Preventive Actions to eliminate quality issues.

Importance of QA

- Prevents defective products.
- Improves product reliability.
- Protects patient safety.
- Reduces manufacturing losses.
- Maintains regulatory compliance.
- Builds customer confidence.

Quality Control (QC)

→ Quality Control (QC) is a part of quality management that focuses on testing and inspection to ensure products meet specified quality standards.
→ QC is mainly concerned with detecting defects.

Objectives of Quality Control

1. Verify product quality.
2. Detect defective materials.
3. Ensure safety and efficacy.
4. Maintain consistency.
5. Support Quality Assurance.

Scope of Quality Control

- Raw material testing
- In-process testing
- Finished product testing
- Stability studies
- Environmental monitoring
- Documentation and record keeping

Elements of Quality Control

1. Raw Material Testing

- Identification tests
- Purity tests
- Quality verification

2. In-Process Quality Control

- Weight variation
- Hardness test
- pH determination

- Moisture content

3. Finished Product Testing

- Assay
- Dissolution
- Disintegration
- Sterility tests

4. Stability Testing

- Determines product shelf life.

5. Documentation

- Recording analytical results and observations.

Importance of QC

- Prevents release of defective products.
- Ensures patient safety.
- Maintains consistency.
- Meets regulatory requirements.
- Supports product quality assurance.

Quality Assurance vs Quality Control

Quality Assurance (QA)	Quality Control (QC)
Process-oriented	Product-oriented
Prevents defects	Detects defects
Proactive approach	Reactive approach
Focuses on system	Focuses on product
Responsibility of all employees	Responsibility of QC department
Includes GMP, validation, training	Includes testing and inspection
Builds quality into product	Verifies quality of product
Done before and during production	Done during and after production

Good Manufacturing Practices (GMP)

→ Good Manufacturing Practices (GMP) are regulations and guidelines that ensure pharmaceutical products are consistently produced and controlled according to quality standards.

→ GMP is an essential part of Quality Assurance.

Objectives of GMP

1. Ensure product quality.
2. Maintain consistency in production.
3. Prevent contamination and mix-ups.
4. Ensure compliance with regulations.
5. Protect patient safety.

Principles of GMP

1. Premises

- Clean and hygienic buildings.
- Proper ventilation and lighting.
- Suitable layout to prevent contamination.

2. Equipment

- Properly designed equipment.
- Regular maintenance and calibration.

3. Personnel

- Qualified and trained staff.
- Personal hygiene practices.
- Defined responsibilities.

4. Raw Materials

- Approved suppliers.
- Proper testing and storage.

5. Production Process

- Follow SOPs.
- In-process controls.
- Controlled manufacturing environment.

6. Quality Control

- Testing of materials and products.
- Product release only after approval.

7. Documentation

- SOPs
- Batch Manufacturing Records (BMR)
- Equipment logs
- Testing records

8. Storage and Distribution

- Controlled temperature and humidity.
- Proper transportation and labeling.

9. Validation

- Equipment validation
- Process validation
- Cleaning validation

10. Complaints and Recalls

- Investigation of complaints.
- Product recall procedures.

Importance of GMP

1. Ensures patient safety.
2. Produces high-quality medicines.
3. Reduces contamination risks.
4. Prevents manufacturing errors.
5. Improves company reputation.
6. Helps regulatory compliance.
7. Reduces product recalls and losses.
8. Increases customer confidence.