Introduction

Quality control and quality assurance



Quality control and quality assurance make complementary contributions to product quality.

Concept and Evolution of Quality Control (QC)

Concept of Quality

- Quality means that a product consistently meets the required standards for identity, purity, strength, safety, effectiveness, and performance.
- A high-quality medicine should produce the expected therapeutic effect without causing unnecessary harm.
- Quality should be maintained throughout manufacturing, storage, transportation, and distribution.

Concept of Quality Control (QC)

- Quality Control is the part of quality management that checks whether a product meets the required quality standards by performing tests and inspections.

Functions of Quality Control

1. **Testing of Raw Materials**
   - Raw materials are tested before they are used in manufacturing.
   - Only approved materials are released for production.
2. **In-Process Testing**
   - Samples are tested during manufacturing.
   - The tests help ensure that the manufacturing process remains under control.
3. **Finished Product Testing**
   - Finished products are tested according to official specifications.

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- Products are released only after meeting all quality requirements.

4. Documentation

- QC maintains complete records of testing procedures and results.
- Proper documentation provides evidence of product quality.

5. Stability Testing

- Products are tested under different storage conditions.
- Stability studies help determine shelf life and storage requirements.

Evolution of Quality Control

A. Inspection Stage

- Quality was ensured by inspecting only the finished product.
- Defective products were removed after manufacturing.

B. Laboratory-Based Quality Control

- Laboratory testing became an important part of pharmaceutical manufacturing.
- Raw materials, intermediate products, and finished products were tested.

C. Modern Quality Control

- Modern QC uses advanced analytical instruments and validated methods.
- Quality Control follows Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and regulatory guidelines.

Scope of Quality Control

- Testing of raw materials & Testing of packaging materials.
- In-process quality testing.
- Finished product testing & Stability studies.
- Environmental monitoring.
- Calibration of laboratory instruments.
- Validation of analytical methods.
- Documentation and record maintenance.

Concept and Evolution of Quality Assurance (QA)

Concept

- Quality Assurance (QA) is a planned and systematic approach that ensures pharmaceutical products are consistently manufactured according to predefined quality standards.

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- QA focuses on preventing defects rather than detecting them after manufacturing.
- Quality Assurance covers every activity from product development to distribution.

Functions of Quality Assurance

1. Preparation of Standard Operating Procedures (SOPs)

- QA develops and maintains written procedures for all operations.
- SOPs ensure consistency in every activity.

2. Validation

- QA ensures that manufacturing processes, equipment, and analytical methods are validated.
- Validation confirms that processes consistently produce quality products.

3. Documentation Control

- QA reviews and approves quality-related documents.
- Proper documentation ensures traceability.

4. Audits

- Internal and external audits are conducted to verify compliance.
- Audits identify areas requiring improvement.

5. Training

- QA ensures that employees receive proper training.
- Training improves competence and reduces errors.

6. Deviation and Change Control

- QA investigates deviations from approved procedures.
- Changes are evaluated before implementation.

Evolution of Quality Assurance

A. Inspection-Based Quality

- Quality depended mainly on final product inspection.

B. Quality Control Era

- Laboratory testing became an essential quality activity.

C. Quality Assurance Era

- Prevention of defects became the primary focus.
- Documentation and process control became essential.

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D. Quality Management System

- QA became part of a complete pharmaceutical quality system.
- Risk management and continuous improvement became major components.

Scope of Quality Assurance

- Quality system management.
- Documentation control.
- Validation and qualification.
- GMP compliance.
- Training programs.
- Vendor qualification.
- Complaint handling.
- Product recalls.
- Change control.
- Risk management.
- Self-inspection and audits.
- Continuous quality improvement.

Difference Between Quality Control and Quality Assurance

Quality Control (QC)	Quality Assurance (QA)
Focuses on detecting defects.	Focuses on preventing defects.
Product-oriented.	Process-oriented.
Involves laboratory testing.	Involves planning and documentation.
Confirms product quality.	Builds quality into the manufacturing process.
Performed mainly after or during production.	Applied before, during, and after production.

Good Laboratory Practice (GLP)

Definition

- Good Laboratory Practice (GLP) is a quality system that ensures laboratory studies are planned, performed, monitored, recorded, reported, and archived in a consistent and reliable manner.
- GLP ensures that laboratory data are accurate, reliable, and traceable.

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Purpose of GLP

- To improve the reliability of laboratory results.
- To maintain data integrity.
- To ensure regulatory compliance.
- To reduce laboratory errors.

Principles of GLP

A. Organization and Personnel

- Laboratory personnel should be qualified and properly trained.
- Responsibilities should be clearly defined.

B. Laboratory Facilities

- Laboratories should be clean and well organized.
- Separate areas should be provided for different activities to avoid contamination.

C. Equipment

- Equipment should be properly installed, calibrated, maintained, and documented.
- Equipment should be suitable for its intended purpose.

D. Standard Operating Procedures (SOPs)

- Written procedures should be available for all laboratory activities.
- SOPs should be followed consistently.

E. Test and Reference Materials

- Test materials should be properly identified and stored.
- Reference standards should be authentic and properly maintained.

F. Documentation

- All laboratory activities should be recorded accurately.
- Records should be complete, legible, and easily retrievable.

G. Quality Assurance Unit

- An independent Quality Assurance Unit should monitor laboratory activities.
- The unit verifies compliance with GLP requirements.

H. Archiving

- Laboratory records, reports, and samples should be stored securely.
- Records should be retained for the required period.

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