QUALITY ASSURANCE AND QUALITY MANAGEMENT CONCEPTS

INTRODUCTION

- In the pharmaceutical industry, the **quality department** is playing an increasingly pivotal role in running a sustainably profitable business that is also committed to meeting the expectations of the patient and public.
- The implementation of an effective **quality management system** allows manufacturers to meet their ethical and regulatory obligations.
- It is a good business sense to **remove defects, reduce deviation and eliminate waste.**
- **To achieve the highest level of safety, purity and efficacy of drug products, quality management teams are moving beyond quality control (QC) and into Quality assurance (QA**).

1

QUALITY CONTROL

- **WHO QC: The sum of all procedures undertaken to ensure the identity and purity of a particular pharmaceutical**.
- **ISO 9000 defines quality control as "A part of quality management focused on fulfilling quality requirements".**
- The purpose of QC is to **ensure** the **safety** and **efficacy** of a **finished drug product** before released to the public.

- Supporting quality system need to detect whether items such as raw materials, components, containers, labeling and packaging fails to meet pre-existing specifications.
- The **QC department** is responsible for conducting this work as well as testing the **finished product** to **ensure it meets regulatory requirements**.
- For pharmaceuticals, QC may **involve** analytical procedures ranging from **simple substance screening to complex pharmacopoeia monographs.**

RESPONSIBILITIES OF QUALITY CONTROL IN PHARMACEUTICAL INDUSTRY

- Quality
- Efficacy
- Safety
- Compliance

OBJECTIVES OF QUALITY CONTROL

- Establishment of quality standard
- Locating quality deviations
- Evaluating methods and processes of production
- Quick sale of quality goods
- Production of standard quality goods
- Improvement in quality

STEPS IN QUALITY CONTROL

- Devising the control over raw materials
- Fixing standards and specifications
- Exercising control over production operations
- Locating inspection points
- Maintaining quality of equipment
- Maintaining records

FUNCTIONS OF QC

- QC is responsible for the **day-to-day control of quality** within the company.

- This department is responsible for **analytical testing of incoming raw materials** and **inspection of packaging components, including labelling.**
- They conduct **in-process testing** when required, perform **environmental monitoring,** and **inspect operations for compliance.**
- They also conduct the required **tests on finished dosage form**.
- QC plays a major role in the **selection of qualified vendors** from whom raw materials are purchased. **Testing of representative samples** is required, and in many cases, an audit of vendor's operations is necessary to determine their suitability and degree of compliance with GMPs prior to their being approved.
- The environmental areas for manufacturing of various dosage forms are **tested and inspected** by QC department.

ADVANTAGES OF QUALITY CONTROL

- **Improvement** of the **quality of production** and reduction in the production cost.
- **Uniformity** in the **production** and supply of standard quality goods to consumers.
- Offering full return of the price paid by the consumers and giving convenience and satisfaction to consumers.
- **Reduction** in spoiled production and **rejection** from consumers and dealers.
- Promotion of **exports** due to **superior and standard quality production**.
- Reduction in inspection **cost.**
- Making products **popular** in market.

QUALITY ASSURANCE

- Quality assurance involves taking a **proactive approach** to **ensure drug products are made in accordance with manufacturing standards** and met their pre- defined product specifications.

AIM

- For quality and compliance to be achieved **"right the first time"** rather than **depend on detecting problems**.
- To continually improve manufacturing standards, eliminating errors along the way.
- Quality control still has a role to play, but with effective **QA and reliable operational performance during the process,** it becomes a component of the pharmaceutical quality system.

QA ACTIVITIES

- Technology transfer
- Validation.
- Documentation
- Assuring quality of products
- Quality improvement plans

RESPONSIBILITIES OF QA

- The QA department is responsible for ensuring that the quality policies adopted by a company are followed.
- It helps to identify and prepare the necessary SOPs relative to the control of quality. It must determine that the product meets all the applicable specifications and that it was manufactured according to the internal standards of GMP.
- QA also holds responsible for quality monitoring or audit function. QA functions to assess operations continually and to advise and guide them towards full compliance with all applicable internal and external regulations.

ROLE OF QA IN PHARMA INDUSTRIES

1.To establish Quality Audit

Establish the quality management system to describe how the firm complies cGMPs and operates to maintain a state of control.

2. To audit compliance to the Quality System

Audit for compliance to policies and procedures: on paper vs. practice

Report on the performance of the quality system, including trends, that help decision making for targeted actions.

3. To establish procedures and specifications

Ensure that procedures and specifications are appropriate and followed.

Ensure that the procedures and specifications of firms under contract are also appropriate and followed, i.e., maintain control and take responsibility for third-party services providers (contract manufacturers, contract laboratories, etc.)

4. To establish manufacturing controls

Ensure that appropriate manufacturing in- process controls are implemented.

Ensure in-process controls are performed during manufacturing operations and results are satisfactory

5. To perform laboratory tests

Perform laboratory testing of components, containers, in-process materials, packaging materials and drug product using validated methods against scientifically-derived, fit-for-purpose specifications

Approve or reject drug products manufactured, processed, packed, or held under contract by another company, i.e., final product release is not delegated to a contractor

Perform retests or reexamine approved components, drug product containers and closures after long storage or exposure to adverse conditions.

6. To review and approve or reject

Review and approve/reject any document that gives work instructions and set requirements such as procedures, protocols, test methods, and specifications including changes to these documents

Review and approve/reject reprocessing and rework procedures

Review and approve/reject production batch records and make the final decision to release a product lot into commerce.

7. To ensure investigation of nonconformance

Ensure investigation is conducted and root cause is eliminated for production and control record errors, discrepancies, and failure to meet specification, including quality attributes

Review complaints to determine if it relates to a failure to meet specification, if so investigate and report to FDA if it is serious and unexpected

8. To keep management informed

Report on product, process and system risks

Report on outcome of regulatory inspections and ensure responses are complete and managed to verifiable closure

9. To describe responsibilities in writing

Have a complete and compliant procedure that describes responsibilities. Follow the procedure.

10. To remain independent

Ensure there is no conflict of interest between regulatory responsibilities and actual daily activities

Be independent reviewer and approver with respect to manufacturing and process/ product development units.

QUALITY CONTROL	QUALITY ASSURANCE
QC is a set of activities for **ensuring quality in products**. The activities focus on identifying defects in the actual products produced.	QA is a set of activities for **ensuring quality in the processes** by which products are developed.
The goal of QC is to **identify defects after a product is developed** and before it's released.	The goal of QA is to **improve development and test processes so that defects do not arise** when the product is being developed.
Prevention of quality problems through planned and systematic activities including documentation.	The activities or techniques used to achieve and maintain the product quality, process and service.
Qc aims to **identify (and correct) defects** in the finished product. Quality control, therefore, is a reactive process.	Qa aims to **prevent defects** with a focus on the process used to make the product. It is a proactive quality process.
Finding & eliminating sources of quality problems through tools & equipments so that customer's requirements are continually met.	Establish a good quality management system and the assessment of its adequacy. **Periodic conformance audits of the operations** of the system.
The goal of QA is to improve development and test processes so that defects do not arise when the product is being developed. Thus, it is a **corrective tool**	The goal of QC is to identify defects after a product is developed and before its release. Thus, it is a **preventative tool**
Ensures and checks: Quality control is usually the responsibility of a specific team that tests the product for defects.	**Develops and defines:** Everyone on the team involved in developing the product is responsible for quality assurance.
Validation is an example of QC.	Verification is an example of QA.