1. Quality Assurance (QA) Concept

"The sum total of all arrangements made with the object of ensuring that medicinal products are of the quality required for their intended use"

"Quality assurance" is a wide-ranging concept covering all matters that individually or collectively influence the quality of a manufactured product.

Quality assurance therefore incorporates GMP and other factors, such as product design and development.

Functions of QA

QA should ensure that

- Pharmaceutical products are designed and developed as per the requirements of GMP and other associated codes such as those of good laboratory practice (GLP) and good clinical practice (GCP).
- Production and control operations are clearly specified in a written form and GMP requirements are adopted.
- Managerial responsibilities are clearly specified in job descriptions.
- Arrangements are made for the manufacture, supply and use of the correct starting and packaging materials.
- All necessary controls on starting materials, intermediate products, and bulk products and other in-process controls, calibrations, and validations are carried out.
- The finished product is correctly processed and checked, according to the defined procedures.
- Pharmaceutical products are not sold or supplied before the authorized persons have certified that each production batch has been produced and controlled in accordance regulatory requirements.
- Satisfactory arrangements exist to ensure, that the pharmaceutical products are stored by the manufacturer, distributed, and subsequently handled so that quality is maintained throughout their shelf- life.
- There is a procedure for self- inspection and/or quality audit that regularly appraises the effectiveness and applicability of the quality assurance system.
- Deviations are reported, investigated and recorded.

- There is a system for approving changes that may have an impact on product quality.
- Regular evaluations of the quality of pharmaceutical products should be conducted with the objective of verifying the consistency of the process and ensuring its continuous improvement.

Quality Assurance-Highlights

- In process quality checking in manufacturing
- Validation of facilities, equipments, process, products and cleaning
- Complaint handling
- Storage of quality records and control samples
- Stability studies

Activities of QA Department

1. Technology transfer
2. Validation
3. Documentation
4. Assuring quality of products
5. Quality improvement plans

1. Technology Transfer

- ✓ Receipt of product design documents from R & D Department.
- ✓ Distribution of documents to different departments.
- ✓ Checking and approval of documents generated based on R & D documents i.e. batch manufacturing record.
- ✓ Scale-up and validation of product.

2. Validation

- ✓ Preparation of validation plans for facility, equipments/process including cleaning
- ✓ Approval of protocol for validation of facility/equipment/product/process
- ✓ Team member for execution of validation of facility/equipment/ product/process

3. Documentation Control

- ✓ Controlled distribution and archiving of documents
- ✓ Control of changes made by proper change control procedure
- ✓ Approval of all documents

4. Assuring Quality of Products

- ✓ cGMP training
- ✓ SOP compliance
- ✓ Audit of facility for compliance
- ✓ Line clearance
- ✓ In-process counter checks
- ✓ Critical sampling
- ✓ Record verification
- ✓ Release of batch for marketing
- ✓ Investigation of market complaints

5. Quality Improvement Plans

- ✓ To take Feedback from different departments
- ✓ Proposals for corrective and preventive actions
- ✓ Annual Products review
- ✓ Trend analysis of various quality parameters for products, environment and water