

Salient Features of Quality Assurance

Quality Assurance

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

It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

QA is the heart and soul of quality control

QA = QC + GMP

The System of Quality Assurance

- Pharmaceutical products are designed and developed in a way that takes account of the requirements of GMP and other associated codes such as those of good laboratory practice (GLP) and good clinical practice (GCP)

- Product and control operations are clearly specified in a written form and GMP requirements are adopted

The System of Quality Assurance

- Managerial responsibilities are clearly specified in job description
- 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 System of Quality Assurance

- The finished products 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 with the requirements of the marketing authorization and any other regulations relevant to the production, control and release of pharmaceutical products

The System of Quality Assurance

- Satisfactory arrangements exist to ensure, as far as possible, 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

The System of Quality Assurance

- 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

- Quality assurance is independence of manufacturing
- In process quality is checked during manufacturing
- Validation of facilities, equipments, process, products and cleaning as per master plan

Quality Assurance-Highlights

- Complaint handling
- Storage of quality record and control samples
- Stability studies
- Registration of documents

Activities of Quality Assurance Dept. (Functions)

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 research centre
- Distribution of documents received from research centre
- Checking and approval of documents generated based on research centre 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

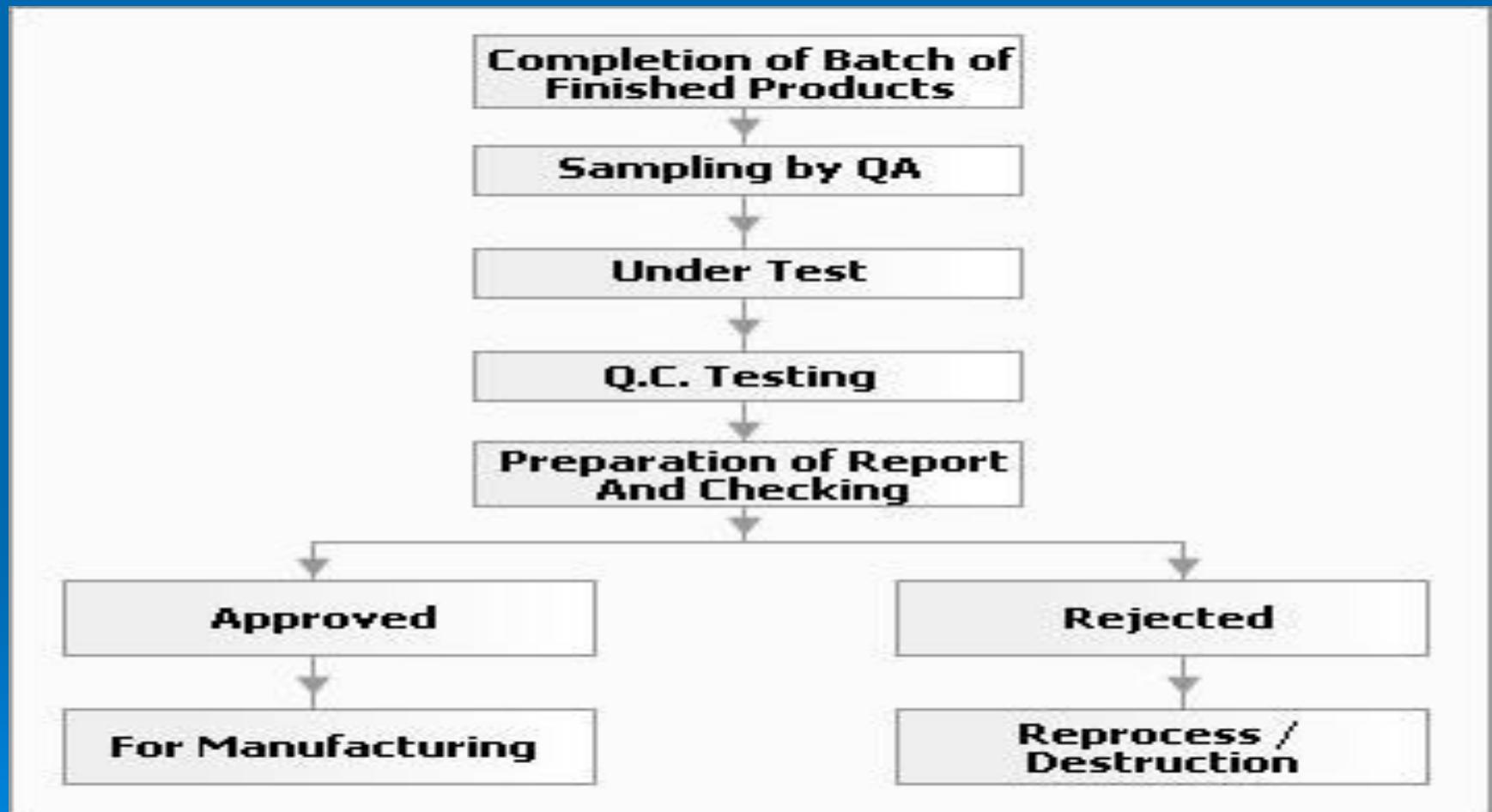
5. Quality Improvement Plans

- Feedback received from the compliance team
- Proposals for corrective and preventive actions
- Annual Products review
- Trend analysis of various quality parameters for products, environment and water

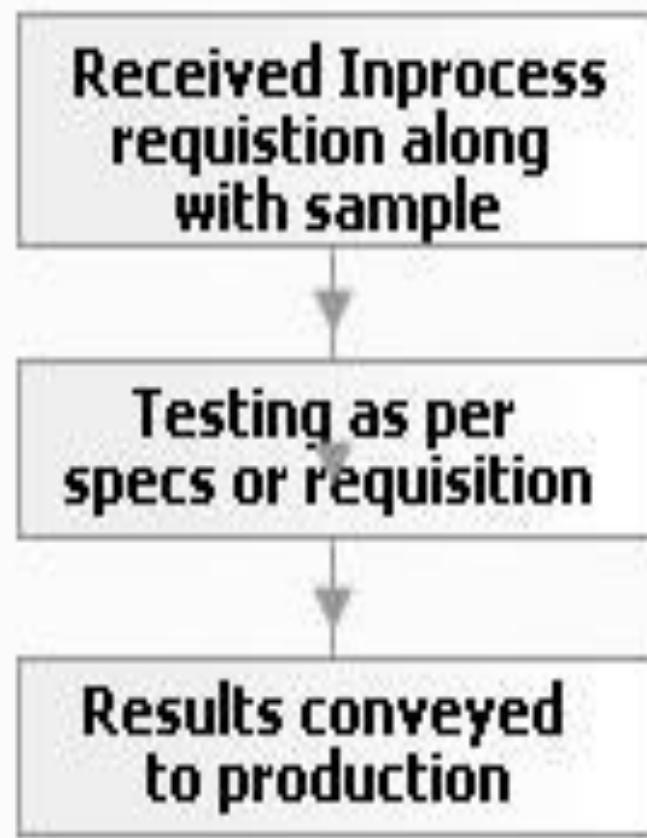
Flow Chart – RM/PM Inspection



Flow Chart-Finished Product Inspections



Flow Chart- In Process Check



Refer supplement notes