
بسم الله الرحمن الرحيم
In The Name Of Allah, The Most Beneficent, The Most Merciful

رَبِّ زِدْنِي عِلْمًا

MY LORD! INCREASE ME IN KNOWLEDGE.

FOOD SAFETY AND QUALITY MANAGEMENT

DHND

YEAR-V

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FSQM L # 61.

FOOD QUALITY MANAGEMENT – FOOD INDUSTRY

Courtesy: Hardik Mistry,
Quality Square Industry Ltd.

Introduction

- 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 /Other Quality Systems

- Raw Material
- Processing
- Equipments
- Manufacturing Plant
- Operators
- Environment
- Manufacturing
- In Process
- Testing
- Finish Product
- Packaging
- Storage
- Dispatch
- Customer

- TOP Management
- Statistical Analysis
- Strict CAPA
- Failure Analysis
- APR
- APQR
- Deviation Management
- Change Control
- OOS Management
- Customer Complaint
- Validation

Quality Assurance

Where QA is Born….?

- Manufacturer (ME) sales my product to the Customer by saying that this product is intended for this with *this this and this* Quality. And you will he happy and satisfied by my Product.
- Now its my responsibility to assure the supply of the claimed Quality (this, this and this) product to the customer.
- But by just controlling Manufacturing operation or person…..I can never assure my customers about Quality which I claimed.
- I must have to look and control over everything related to the making of product like
  - ✓ Raw Material Quality
  - ✓ Ancillary Material Quality
  - ✓ Operational Quality
  - ✓ Equipment and Instrument Quality
  - ✓ Persons engaged in whole operation (Store, QC, QA, Production, Logistics, IT)
  - ✓ Manufacturing and testing Quality etc..

- If I miss to take care any of them, then I cannot give the assurance of my product.
- And if customer is not happy by my product, I will lose him…….

- So to make my customer Happy and Satisfied with my product……Quality Assurance will work over overall manufacturing of my Product.

QUALITY ASSURANCE

FINE QUALITY INPUT ONLY CAN GIVE YOU A FINE QUALITY OUTPUT.

ISO/GMP

ISO
(International Organization for Standardization)

It work in favor of customer
Its focus is on product Quality
ISO consists more Business operations
Optional

GMP
(Good Manufacturing Practice)

It works in favor of Manufacturer
Its focus is on Manufacturing
GMP consists of more technical operations
Mandatory

If you have GMP → 20 – 30 % more work needed to get ISO
If you have ISO → 65 – 75 % more work needed to get GMP

That work and required more work will be the great effort of the QUALITY ASSURANCE

Quality Assurance
is a dynamic process

It is a journey
towards the destination

Quality Assurance Highlights

- According to QA, 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.
- 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.

Cont....

- The finished products is correctly processed and checked according to the defined procedures.
- 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 products.
- 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.

Cont....

- 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.
- Evaluation and Analysis of the Deviations, Out of Specification results and Change Controls during the Manufacturing
- Complaint handling
- Documentation of the process from staring material to the end user and its storage.
- Stability studies
- Registration of documents

The 5 M's of Quality

- Man
- Material
- Machinery
- Manuals/Methodology (SOP)
- Motivation

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Factors influencing Quality

Pre analytical	Analytical	Post analytical
Right specimen	Laboratory professionals	Recording
Right collection	Reagents	Interpretation
Right labeling	Equipment	Turnaround time
Right quantity	Selection of test - SOP	Report to right user
Right transport	Records	
Right storage	Bio-Safety	

QA Activities

1.Technology transfer

2. Validation

3. Documentation

4. Assuring quality of products

5. Quality improvement plans

Cont....

1 – Technology transfer

- Receipt of product design documents from research centre
- Receipt of the trial and error data and its final evaluation
- 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

Cont....

2– Validation

- Preparation of Validation Master plans for facility/equipments/process Utility, Cleaning and all the sections of the validation
- Approval of protocol for validation of facility/ equipment/product/ process/Utility
- Team member for execution of validation of facility/equipment / product/ process
- Final approval of the facility/ equipment/product/ process/Utility validation

Documentation

- Main objective

  To establish, monitor and record "Quality" for all aspects of Good Manufacturing Practices (GMP) and other Quality System pertaining

- Type of documents
  - ✓ Standard operating procedures
  - ✓ Protocols of tests,
  - ✓ Results
  - ✓ Reports

" IF you have not documented it You have not done it"

Laboratory records

- Description and identification of sample received
- Description of method of testing
- Record of all data secured in the course of the test
- Record of test results and how they compare with standards of identity, strength and quality
- Record of all deviations and modification of test
- Record of standardization of reference standards
- Record of calibration of equipments

Cont....

3 – Documentation Control

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

Standard Operating Procedure(SOPs)

An authorized written procedure giving instructions for performing operations not necessarily specific to a given process, product or material (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection).

Cont...

- Standard operating procedures describe in a detailed form the activities performed in the laboratory
- Provide uniformity, consistency and reliability in each of the activities performed in the laboratory
- Reduce systematic errors
- Provide training and guidance for new staff

SOPs should be....

- Written instructions that specify how a test or procedures is to be performed.
- How a piece of equipment is operated, maintained and calibrated.
- Describes "Standard" approved procedures.
- Revision … when planned changes are made or annually
- Original – maintained in a central file.
- Copies – distributed to locations.
- Written by the person performing the procedure or who knows the procedure well.
- Supervisor review SOPs for completeness and content.
- QA or QC staff approval

Cont....

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

Cont....

5 –Quality improvement plan

- Feedback received from the compliance team
- Customer complaint history
- Proposals for corrective and preventive actions
- Annual Products review
- Trend analysis of various quality parameters for products, environment and water
- Review of the Deviations, Change Controls, Out Of Specifications and Failures.

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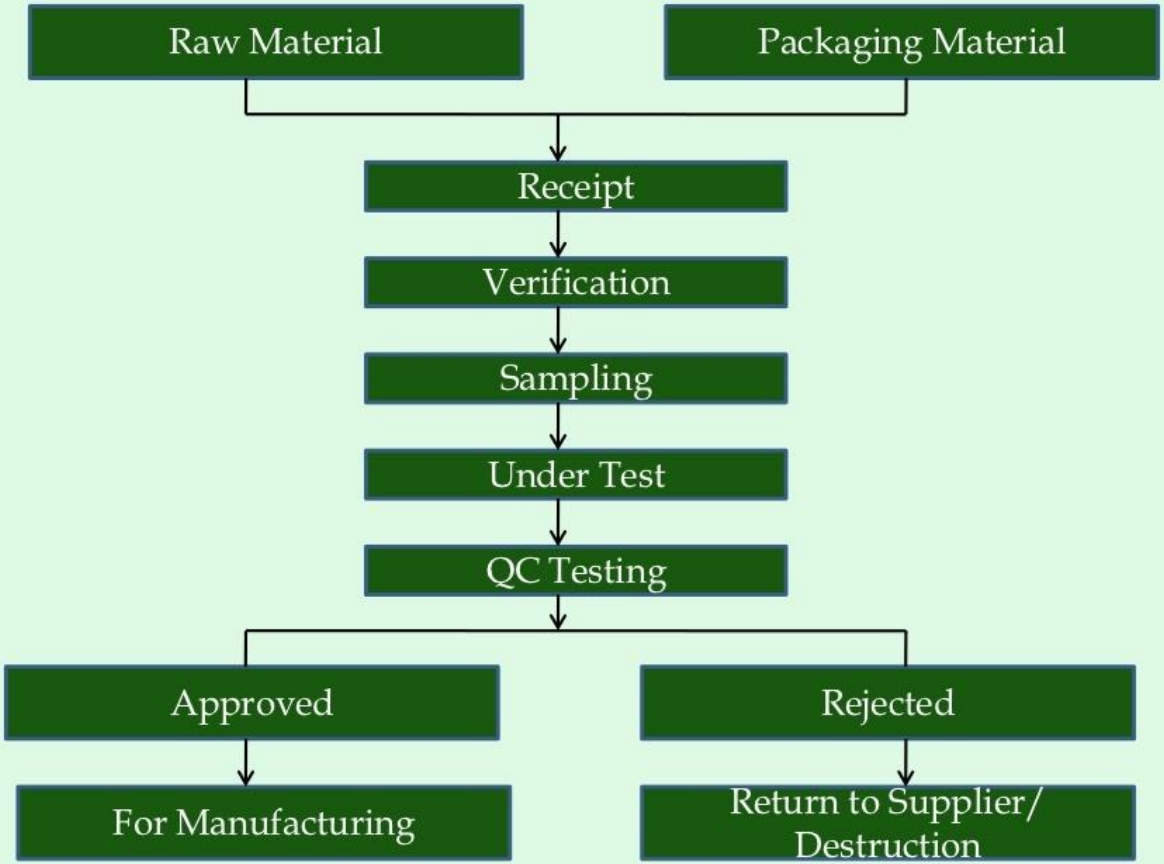
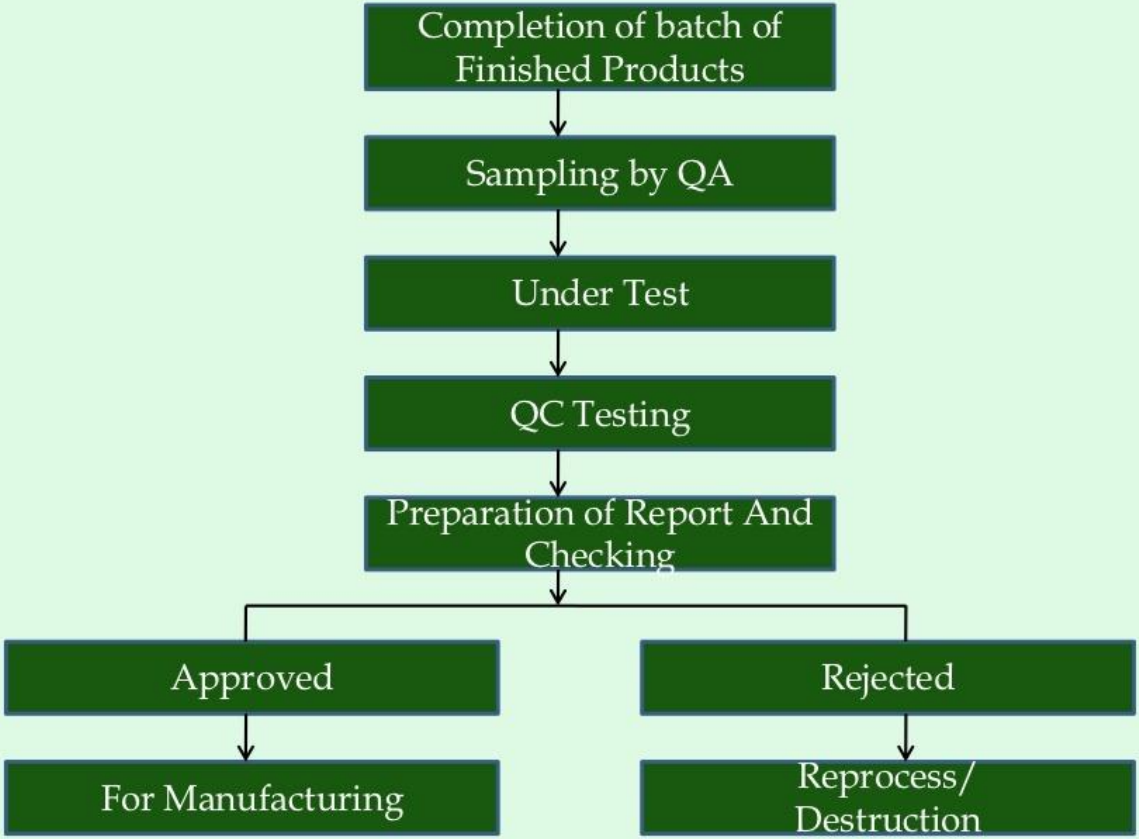
Courtesy: Hardik Mistry, Quality Square

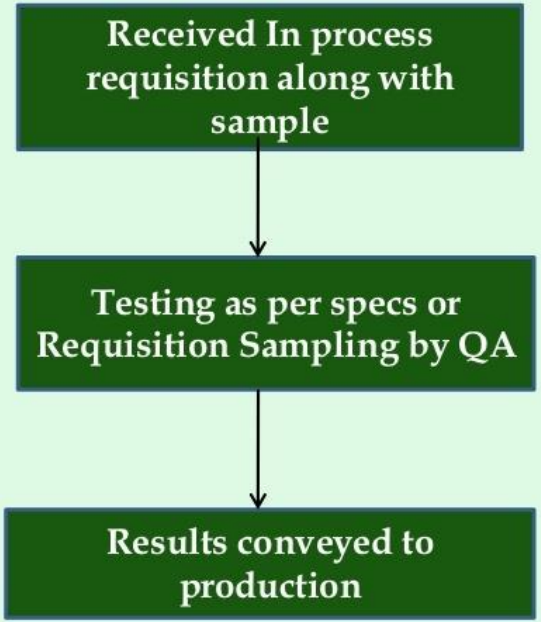
Flow Chart RM/PM Inspection

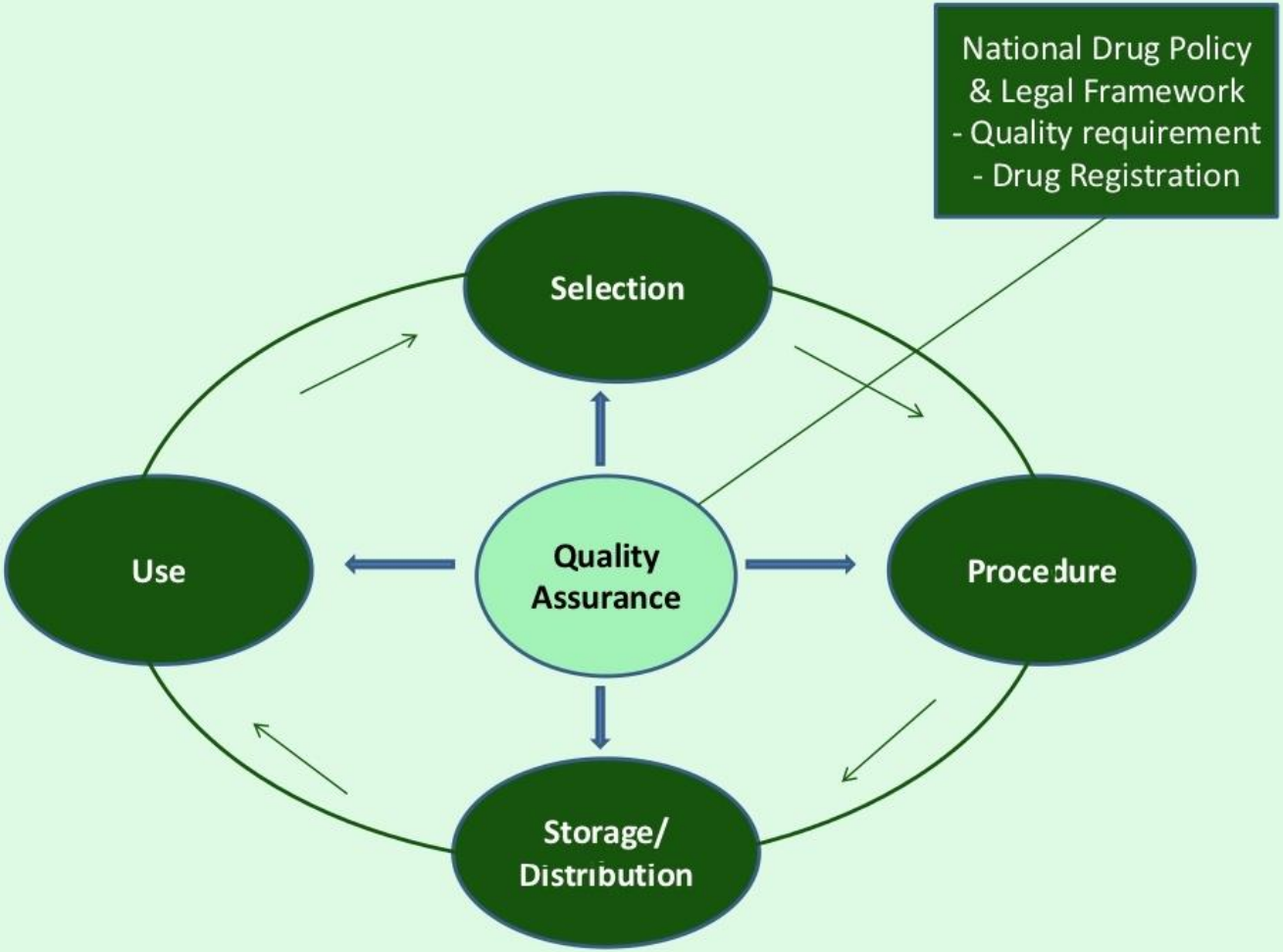


Flow Chart Finished Product Inspection



Flow Chart In process Check




National Drug Policy
& Legal Framework
- Quality requirement
- Drug Registration
Selection
Use
Quality
Assurance
Procedure
Storage/
Distribution

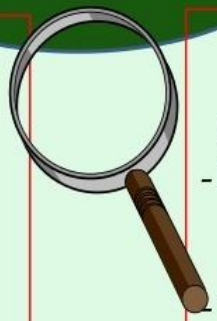
Business

- Establish if the company is manufacturer or wholesaler;
- Assess the size of business in terms of staff. Capital value, Sales turnover. etc.

Manufacturing

- Ensure GMP compliance
- WHO Certification can be used;
- Crosscheck with QA system description

QA Verification



Quality

- Evaluate QA System:
- GMP requires companies to have QC laboratories

Product

Formulate decision from

- Regulatory status of a product with well-established DRS;
- WHO Certification Scheme;
- Therapeutic equivalence

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Quality Assurance and Standards

Standards are the key to effective quality management
They may be international, national, organizational or project standards.

- Product standards
- Process standards
- In process Standards
- Raw material and Packaging Material Standards
- Testing Standards
- Equipment and Instrument Standards
- Working and Reference Standards

Importance of Standards

- Encapsulation of best practice- avoids repetition of past mistakes.
- They are a framework for quality assurance processes - they involve checking compliance to standards.
- They provide continuity - new staff can understand the organisation by understanding the standards that are used.

Documentation Standards

- Particularly important - documents are the tangible manifestation of the softcopies.
- Documentation process standards
  Concerned with how documents should be developed, validated and maintained.
- Document standards
  Concerned with document contents, structure, and appearance.
- Document interchange standards
  Concerned with the compatibility of electronic documents.
- Document identification standards
  How documents are uniquely identified.
- Document structure standards
  Standard structure for project documents.
- Document presentation standards
  Define fonts and styles, use of logos, etc.
- Document update standards
  Define how changes from previous versions are reflected in a document.

Quality Planning

- A quality plan sets out the desired product qualities and how these are assessed and defines the most significant quality attributes.
- The quality plan should define the quality assessment process.
- It should set out which organisational standards should be applied and, where necessary, define new standards to be used.

Quality plans

- Quality plan structure
  - Product introduction;
  - Product plans;
  - Process descriptions;
  - Quality goals;
  - Risks and risk management.
- Quality plans should be short, succinct documents
  - If they are too long, no-one will read them.

Quality Control

- Component of a QA program
- Procedure control
- QC process involves checking all the operational procedures to make certain they are performed correctly
- The QC chemists must ensure that they meet standards at all times

- Right to test all the levels….No evaluation of the result
- QA will evaluate the all the testing results at all the levels and give approval for the further process.

Quality Review

- This is the principal method of validating the quality of a process or of a product.
- A group examines part or all of a process or system and its documentation to find potential problems.
- There are different types of review with different objectives
  - ✓ Annual Product Review
  - ✓ Annual Product Quality Review
  - ✓ Document Review

Review results

- Comments made during the review should be classified
  - No action
    No change to the Product, Process or Document
  - Refer for Improve
    Should correct an identify root cause of the problem
  - Reconsider overall design
    Some overall judgement must be made about the most cost-effective way of solving the problem;

Quality Assurance Equipment Criteria

- Selection
- Purchase / Acquisition
- Installation
- Calibration / Validation
- Maintenance - Service and repair
- Replacement

Everyone is Quality Assurance