QUALITY ASSURANCE & QUALITY MANAGEMENT CONCEPTS

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Definitions

Quality Assurance (QA)—Sum of all activities and responsibilities required to ensure that the medicine that reaches the patient is safe, effective, and acceptable to the patient

Quality Control (QC)—Process concerned with medicine sampling, specifications, and testing, and with the organization's release procedures that ensure that the necessary tests are carried out and that the materials are not released for use, nor products released for sale or supply, until their quality has been judged satisfactory

Definitions

Quality Management (QM)—

A quality management system is a management technique used to communicate to employees what is required to produce the desired quality of products and services and to influence employee actions to complete tasks according to the quality specifications.

Good Manufacturing Practices (GMP)—

Performance standards that WHO and many national governments established for pharmaceutical manufacturers covering, for example, personnel, facilities, packaging, and quality control.

What is Quality

Quality is “totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs”.

- The ability to make the same thing the same way, over and over again.
- Customer buys today is same as what they bought last week or will buy next week.
- Product meets customer’s expectations 100% of the time.

Why Is Quality Important ?

Business success may simply be the extent to which any organization can produce a higher-quality product or service than its competitors are able to do at a competitive price.

When quality is the key to a company's success, Quality Management system allow organizations to:

- Keep up with and meet current quality levels.
- Meet the consumer's requirement for quality.
- Retain employees through competitive compensation programs.
- Keep up with the latest technology.

Introduction:

Goals of QA Programs:-

- To make certain that each medicine reaching a patient is safe, effective, and of standard quality.
- Obtaining quality products that are safe and effective through structured selection and procurement methods
- Maintaining quality products through the appropriate storage, distribution, monitoring, and use by prescribers, dispensers, and consumers

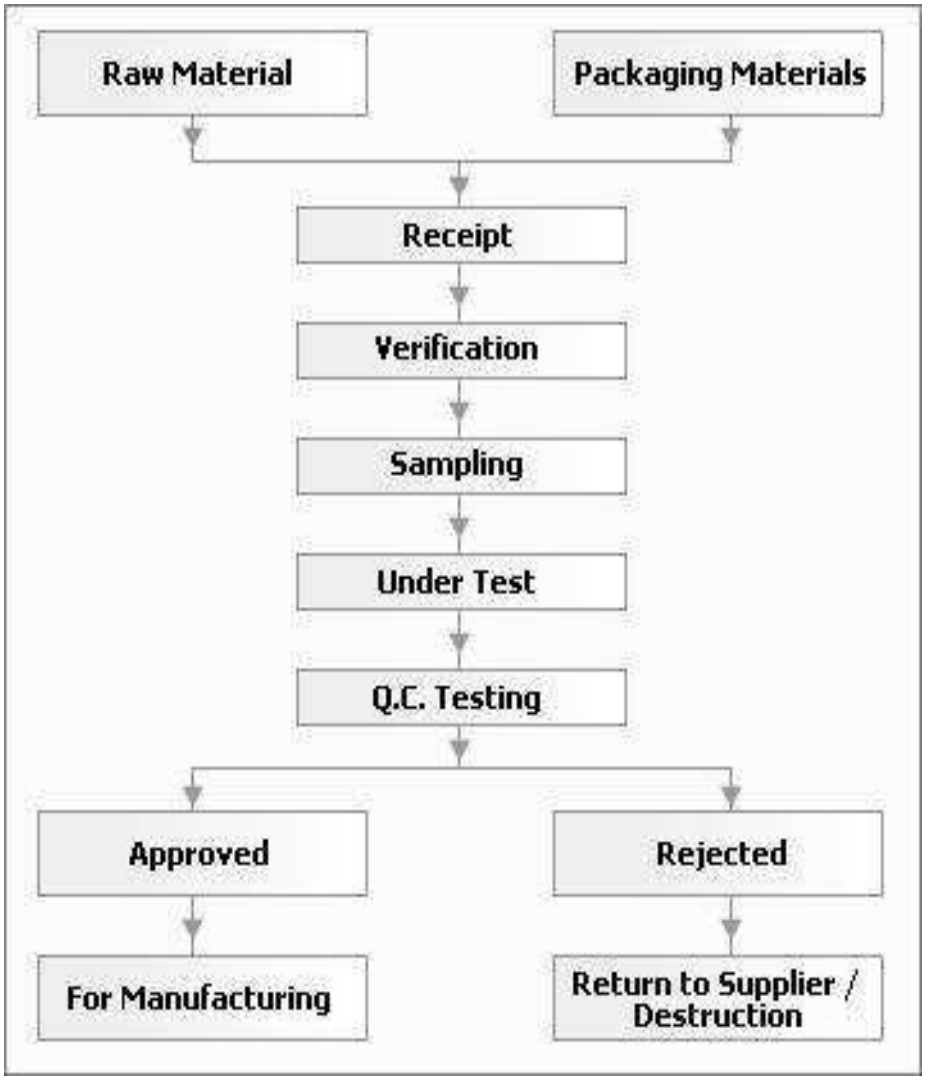
Characteristics of a QA Program

- Medicines are selected on the basis of safety and efficacy, in an appropriate dosage form with the longest shelf life.
- Suppliers with acceptable quality standards are selected.
- Medicines received from suppliers and donors are monitored to meet quality standards.
- Medicine packaging meets contract specifications.

Characteristics of a QA Program

- **Repackaging activities and dispensing practices should maintain quality.**
- **Adequate storage conditions in all pharmaceutical areas are maintained.**
- **Transportation conditions are adequate.**
- **Product quality concerns are reported and monitored.**

Total Procedure



How Is Quality Assessed?

- INSPECTION of raw materials and API on arrival.
  - Visual inspection
  - Product specification review (including expiry dates)
- LABORATORY TESTING for compliance with pharmacopoeial standards
  - International Pharmacopoeia
  - European Pharmacopoeia
  - U. S. Pharmacopeia
  - British Pharmacopoeia
  - National Pharmacopoeia
- BIOAVAILABILITY DATA

How Is Quality Assured?

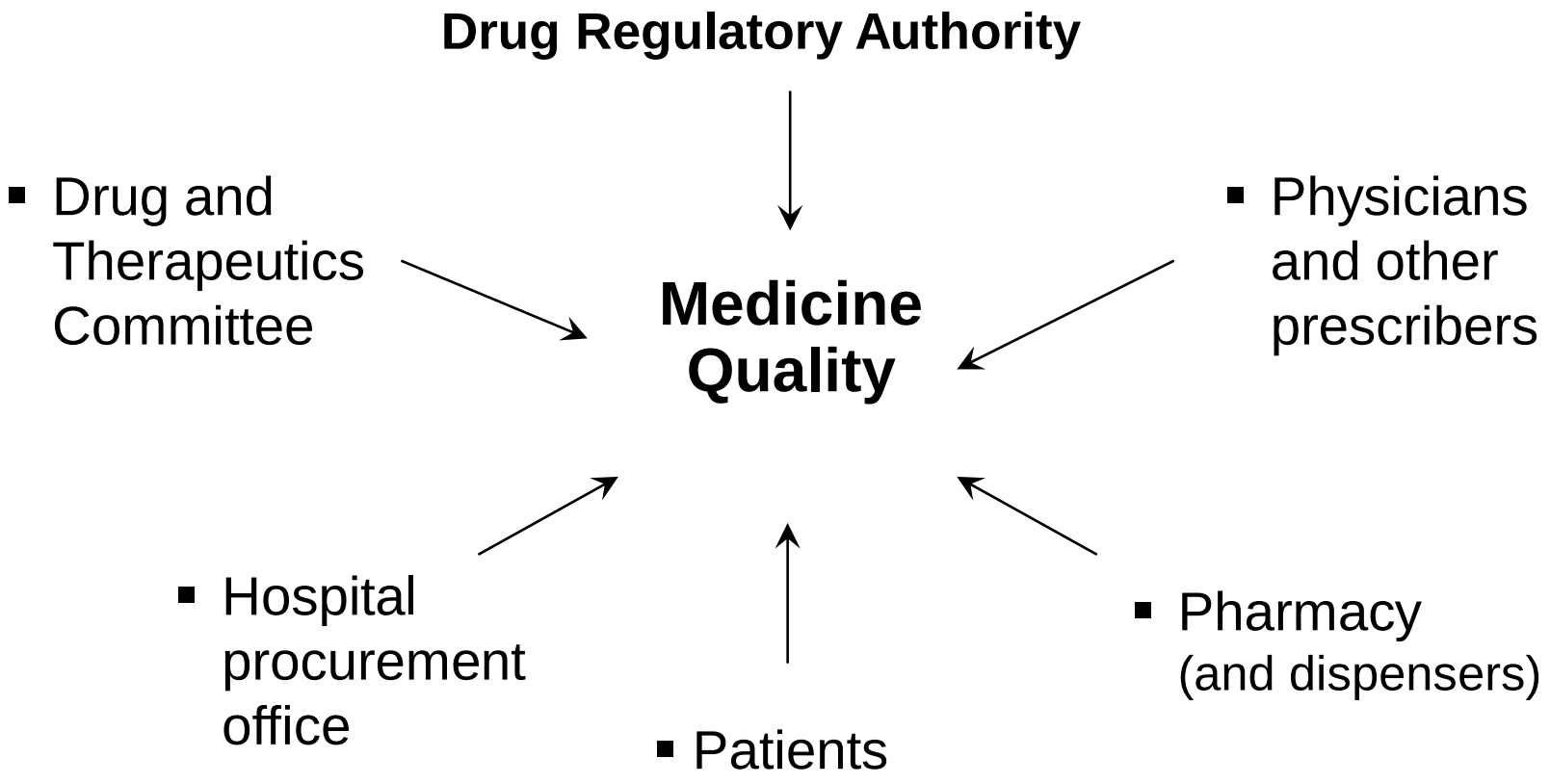
- **Product selection**
  - Long shelf-life.
  - Acceptable stability.
  - Acceptable bioavailability.
- **Selection of appropriate suppliers**
  - Supplier pre-qualification.
  - Request samples from new suppliers.
  - Request specific reports and data for certain medicines (e.g., bioavailability and stability studies).
  - Collect and maintain information on supplier performance.
- **Product certification**
  - GMP certificate of manufacturer.
  - Product/batch certification (COA).
  - Random local testing.

How Is Quality Assured?

Some other aspects:-

- Appropriate storage, transport, dispensing, and use procedures.
  - Pharmaceutical distribution and inventory control procedures.
  - Provision for appropriate storage and transport including adequate temperature control, security, and cleanliness.
  - Avoidance of repacking unless quality control is required

Who Ensures Medicine Quality?



Elements of Pharmaceutical Quality System:

Fundamental elements for effective pharmaceutical quality systems are as follows:

- Managerial review of process performance and product quality.
- Process performance and product quality monitoring system.
- Corrective action and preventive action (CAPA) system.

Aims Of Quality Management

Management responsibility:

Leadership is essential to establish and maintain a company-wide commitment to quality and for the performance of the pharmaceutical quality system. Management has the responsibility to achieve quality related goals as per the quality policy.

- There must be a clear understanding and unambiguous set of authority and responsibility at all levels including individual and collective role.
- Strict commitment toward the quality objectives should be demonstrated.
- Management should participate in the design, implementation, monitoring, and maintenance of an effective pharmaceutical quality system.

Aims Of Quality Management

Continuous improvement in process performance and product quality:

- Product quality depends on appropriate design of quality attributes during product development phase.
- Technical knowledge or specification, control strategy and validation approaches should be effectively transferred within or between manufacturing sites for commercial manufacturing.
- Product discontinuation aspects include retention of relevant documents, samples and review of product assessment, complaint handling and stability related problems as per regulatory provisions.

QUALITY CONTROL:

- A system of maintaining standards in manufactured products by testing a sample of the output against the specification.
- ISO 9000 defines quality control as "A part of quality management focused on fulfilling quality requirements"
- It is that part of GMP concerned with sampling, specification and testing, documentation and release procedures which ensure that the necessary and relevant tests are performed and the product is released for use only after ascertaining it’s quality.

RESPONSIBILITIES OF QC:

- QC is responsible for day to day control of quality within the company
- QC is responsible for analytical testing of incoming raw materials and inspection of packaging components, including labeling
- 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.
- The environmental areas for manufacturing of various dosage forms are tested and inspected by QC department

GOOD MANUFACTURING PRACTICE (GMP)

Good Manufacturing Practice is a part of quality assurance which ensure that the products are consistently produced and controlled according to quality standards appropriate to their intended use.

- GMP – A set of principles and procedures which, when followed by manufacturers for the therapeutic goods, helps ensure that the products manufactured will have the required quality
- It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

UNDER GMP:

a) All manufacturing processes are clearly defined, systematically reviewed for associated risks in the light of scientific knowledge and experience, and shown to be capable of consistently manufacturing pharmaceutical products of the required quality that comply with their specifications;

b) Qualification and validation are performed;

c) All necessary resources are provided, including:

- sufficient and appropriately qualified and trained personnel,
- adequate premises and space,
- suitable equipment and services,
- appropriate materials, containers and labels,
- approved procedures and instructions,
- suitable storage and transport,
- Adequate personnel, laboratories and equipment for in- process controls;

LISTS OF IMPORTANT DOCUMENTS IN GMP

- Policies
- Standard operating procedures SOP
- Specifications
- Master formula records MFR
- Batch manufacturing record BMR
- Manuals
- Master plans/Files
- Validation protocols
- Forms and formats
- Records


Thank
You