Quality Assurance and Quality Management

Kajal Baviskar
Dept. of Pharm. Chemistry
K.K.Wagh College of Pharmacy


Production
Quality Control
Quality Assurance
Technical Services/Validation Dept
Regulatory Affairs
Medical Affairs
Training & Development
Research and Development/
New Product Development
Administration
Human Resources
1-Marketing & Sales
2-International Marketing/Export
Business Development
Supply Chain
1-Material Purchase/Import
2- Ware House
3-Distribution/Commercial Dept
4-Production planning
Engineering

Quality assurance and quality management concepts

Quality Assurance

Quality Control

GMP

- Quality should be built into the product and testing alone cannot be relied onto ensure product quality.

- Quality management is the act of overseeing all activities and tasks that must be accomplished to maintain a desired level of excellence.

- This includes the **determination** of a quality policy, creating and implementing quality **planning** and assurance, and quality control and quality improvement

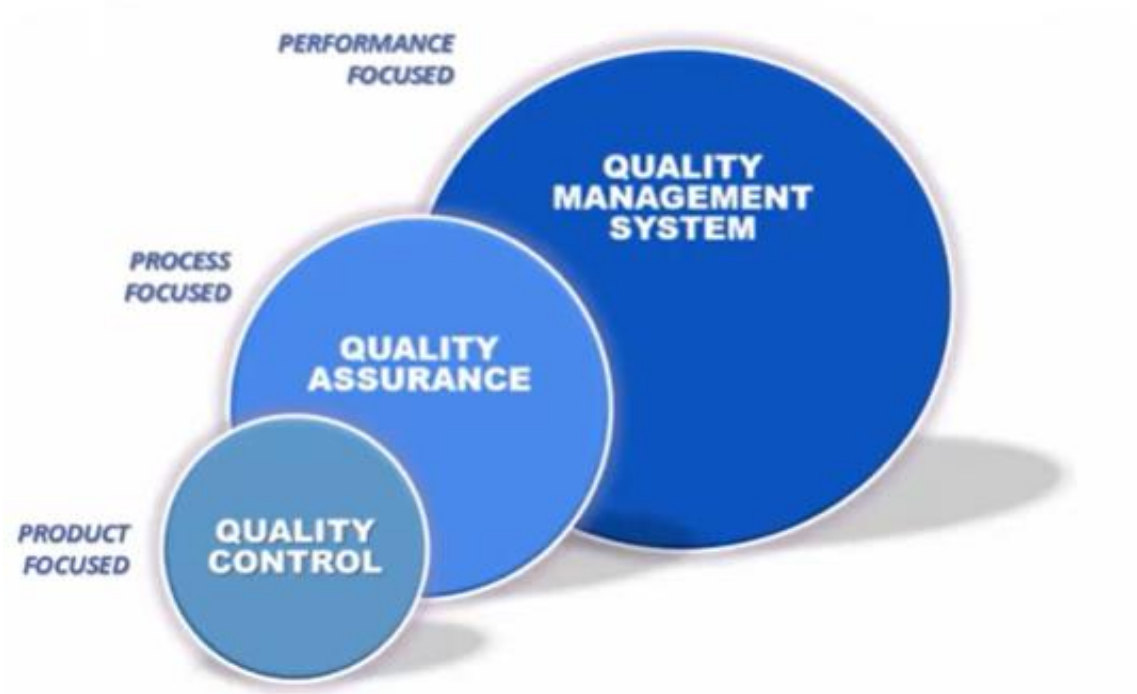

QUALITY RELATIONSHIPS
Quality Management
Quality Assurance
GMP
Quality Control
GMP
QC
QA
8

Umbrella of Quality

Quality management system
All organizational processes that ensure quality

Quality assurance
All the planned activities that can be demonstrated to provide confidence that a product or service will fulfill requiremnts for quality

Quality control
The inspection of implemented techniques and activites to ensure they are fulfilling requirements for quality


PERFORMANCE FOCUSED
QUALITY MANAGEMENT SYSTEM
PROCESS FOCUSED
QUALITY ASSURANCE
PRODUCT FOCUSED
QUALITY CONTROL

Quality Assurance

Quality assurance (**QA**) is a way of preventing mistakes and defects in manufactured products and avoiding problems when delivering products or services to customers.

According to WHO, quality assurance is a wide-ranging concept covering **all matters** that individually or collectively **influence the quality** of a product. It is totality of the arrangement made with the object of ensuring that pharmaceutical products are of quality required for their intended use.

- Q.A deals with **all matters** related to **quality** of product.
- Quality of the medicine /product must meet the requirements of the intended use or as an required by the **ultimate/end user**.
- It is wide ranging concept covering many aspects which are outside the scope of Q.C./GMP etc.
- It is **sum total of organized arrangement** made for producing a quality product.

Quality =

A pharmaceutical product which meets following 5 characteristics can be accepted as a quality product.

- ✓ Identity
- ✓ Strength
- ✓ Safety
- ✓ Purity
- ✓ Efficacy

Identity

- Name and content
- If you call name of the product it will refer to a specific product only containing specific ingredients.

Issues:

- Product with same name but different formulations.

- Product with same name but different API

Therefore product identity may be referred as:

Name of the product

Type of formulation

Name and quantity of API in a unit dose.

Strength

- Strength of pharmaceutical unit dose.
- “ each tablet contains 500 mg paracetamol”

Safety

- i.e. safety of the ultimate user or patient.

When a patient takes drug, he may experience any one of the foolowing:

1. He gets no desired effect.
2. He gets partial desired effect
3. He gets unexpected, undesired effect (unknown side effects)
4. He gets expected undesired effect (known side effects)
5. He gets desired effect.

A product which gives both 4^{th} and 5^{th} or only 5^{th} effect may be considered as safe product.

Purity

- Product is free from any cross contamination..

Wide ranging concept??

- Pre production activities: procurement of materials, storage etc.
- Production and Q.C activities.
- Post production activities: distribution and storage
- Also activities carried out and all decision taken by people at various levels and various times which have effect on the quality of product.

Ultimate User??

Ailing person/Patient

Interests of user:

- Effective medicine/ reliability of results
- Reasonable price
- Easy availability.

Sum total of organized efforts??

All efforts should have contribution to the quality of product.
No duplication of effort.
Activities should be value adding and not cost adding.

Activities of QA

- Products are designed and developed taking into account GMP, GLP, GCP etc.
- SOP should be maintained.
- Calibrations and validations to be carried out time to time.
- Finished products are correctly processed and checked.
- Products not to be sold or supplied before certification.
- Self inspection/Quality audit

Responsibilities of QA dept.

- Ensuring quality policies adopted by the industry are followed.
- Products meets all the specifications and GMP are followed.
- Audits


Hygiene
in
Production
Traceability
GMP
Quality
Management
Complaints
and
Recall
Suitable Facilities
and
Qualified Personnel

- GMP is a part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by marketing authorisation.

- GMP is a part of Q.A
- Main function is to produce quality products consistently
- GMP must deal with both production and Q.C related issues

Activities of GMP

- All manufacturing process be clearly defined.
- Critical steps of manufacturing process and any significant changes made to the process validated.
- All necessary facilities to be provided.
- Training of operators
- Records to be maintained
- Proper storage and distribution
- System to recall any batch as and when required.

Quality control

Definition

- Q.C is a part of GMP concerned with sampling, specifications, testing with the organization, documentation and release procedures which ensure that necessary and relevant test are actually carried out and that materials are neither released for use nor products release for sale or supply.

- QC labs
- Sampling
- Retained samples
- Records
- Validation

Q. C labs

- Chemical testing laboratory
- Instrumental Analysis lab
- Microbiology and toxicology lab
- Provision for retained samples
- Documentation room
- Books
- Trained personnel
- SOP’s

Sampling

Sampling area

Sampling of sterile products

Sampling procedure

Reference samples

Sampling of I.P.Q.C materials

Sampling of bulk finished and packed materials.

- Sampling area

Separate sampling area

Poisons/explosives

Packaging material

- Sampling of sterile pdts

Aseptic area

Sterile equipments

- Sampling procedure

Representative samples

Containers to be marked

Clean equipment

Containers to be opened, sampled, and resealed to prevent contamination

Sample a component from the top, middle, and bottom of its container

* Not to be composited

Containers should bear
Name of material
Batch/lot no.
Number of contaibner from which sample has been taken
Sign of person
Date

Containers from which samples have been taken should be marked.

- Reference samples:

Sm/fp which can be stored for future anlaysis if the need arises during shelf life of the batch concerned.

- Retained samples:

Samples collected from batch for referring packing style, batch no., mfg date, exp date, patient leaflets or other info.

- In some cases, retained samples may be skipped.

Each lot of very API to be stored in qs to carry out all tests to be retained for 3 months after date of expiry of last batch produced from that active ing.
Samples of finished formulations to be stored in same/simulated containers in which drug has been actually marketed.

- As per WHO

Retained samples: 1 year after expiry date

FP final packaging

If exceptionally large packages: smaller samples may be stored.

API samples should be retained for 1 year beyond expiry.

Other : minimum of 2 years

Size of retention samples: permit atleast 2 full examinations.

- Sampling of IPQC materials:

??

Monitor the progress of manufacturing process

If necessary, adaptation of manufacturing processes to ensure that the product confirms to its specifications.

Control of equipment

Control of env.

Performed
during a processing step
or
After end of process

“ identify and follow all the changes that may occur during applied technological procedures.

Thank you