ROLE OF QA
IN
PHARMA INDUSTRY

Basic definitions

- **Quality Management :**

  Aspect of Management function that defines & implement Quality Policy that is over all intentions & direction regarding Quality.

- **Quality Assurance :**

  It is wide ranging concept covering all matters that individually & collectively influence the quality of products.

- **Quality Control :**

  Concerned with Sampling, Specification & testing, documentation and release procedures. It is also involved in decision making regarding quality of product.

- **Inspection :**

  Checks the samples as per standard sample or specification.

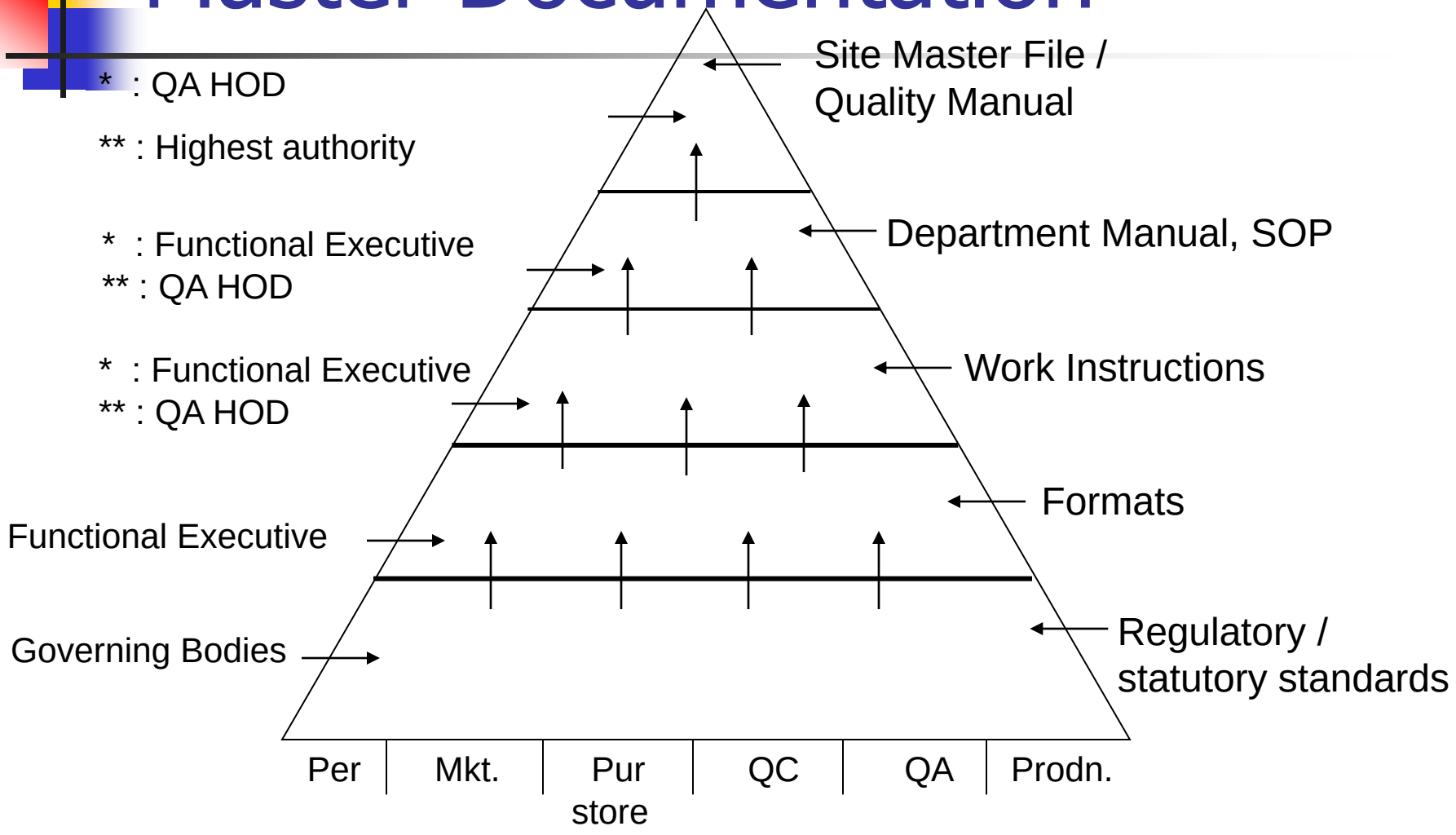
QA should ensure

- Pharmaceutical products are designed & developed considering GMP, GCP & GLP requirements.
- Production & control operations are clearly specified.
- Managerial responsibilities are clearly specified.
- Arrangement are made for manufacture, supply & use for correct RM / PM.
- Necessary control on starting material intermediate product, bulk products, calibration & validation carried out.
- Finished Products are correctly processed & checked.
- Control on despatch of products.
- Handling & storage of goods after despatch & control on returned goods.
- Handling of market complaint.
- Self inspection.
- Training.

Design & Development of Product

- Preparation of tentative Bill of material & Product / material specification.
- Vendor evaluation.
- Preparation of trial batches & Stability testing.
- Finalisation of shelf life and preparation of licence document.
  i.e. Stability data.
  Finished product specification.
  Licence document.
- Preparation of artwork.
- Vendor approval for printed packing material.
- Working of final Bill of material MFR, BMR, finished product specification.
- Preparation and execution of process validation.
- Stability of production batches.

Master Documentation



Responsibilities / Authorities

- QA Head is important authority for any technical issue & reports to topmost authority.
- Separate reporting of QA head & production Head is essential .

Responsibilities of QA Head

- Authorisation of master documents.
- Control on manufacturing environment
- Plant Hygiene.
- Process validation & calibration.
- Training.
- Vendor evalution.
- GMP compliance.
- Self Inspection.

Responsibilities of Production Head

- Manufacture the product as per GMP norms.
- Execution of inprocess controls.
- Batch Record & log book evalution .
- Training to production personnel.
- Maintenance of premises & equipments.

Responsibilities QC Head

- Approve or rejects starting materials, inprocess products & finished products.
- Prepare sampling instructions, specifications, test methods & calibration procedures.
- Maintenance of department & Instruments.
- Calibration of instruments.
- Analytical method validation.
- Training.

Material control

- Vendor Evalution.
- Vendor Approval.
- Vendor rating.
- Rejection analysis.

Validations

- Validation Master plan.
- Process validation.
- Cleaning validation.
- Analytical Method validation.
- Equipment validation.

Calibration

- **Calibration :** The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.

Calibration

- **Accuracy :**Is closeness of test results to standard value.
- **Precision :** It is degree of variation between different readings of same standard value.

Calibration of process regulating equipment.

Calibration of QC Instruments.

Yearly plan of Calibration.

Approval Of

- MFR : BMR : BPR
- Raw material specification.
- Packing material specification.
- Finished product specification.
- Instrument operating & calibration procedure.

Inprocess Checks (IPQA)

- Material Dispensing.
- Process of batch.
- Packing.
- Despatch.
- Spot inspection at distribution.

Sanitation & Hygiene

- Class of area.
- Cleaning schedules.
- Types of disinfects.
- Personal Hygiene.
- Medical checkup.
- Pest control.

Self Inspection

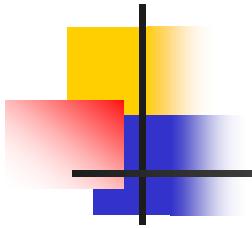
- Self inspection team.
- Check list.
- Areas to be covered.
- Follow up inspection.

Complaint Handling

- Types of compliant
  - Major
  - Minor
  - Critical
- Handling of complaints.
- Review of complaints.

Training

- Induction training.
- On job training.
- Clean Room training.



Thank You !