Quality Assurance & Quality Control:

In Pharmaceuticals & Healthcare Industries

Presented By: Mr. Pradipta Kumar Sahoo
Golden Cross Pharma (A Unit of Cipla Ltd.)
“Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction, and skillful execution; it represents the wise choice of many alternatives.”

—William A. Foster
Why Quality is important in pharmaceuticals?

- The pharmaceutical environment today is changing quickly due to globalization, increased competition, cost constraints, demands for efficiency, development of international regulation, supply chain complexity, and product/process complexity. In this fast-changing environment, the people and companies that learn to adapt will prosper.

- To manufacture & deliver consistently zero-defect products to the patients.

- The quality, efficacy and safety attributes of products must be ensured so that the consumer health is not compromised.
Impacts of ignorance on Quality

- Manufacturing process
- Packaging
- Transportation
- Storage condition

MEDICINE QUALITY

- Lack of therapeutic effect:
  - Prolonged illness
  - Death
- Toxic and adverse reaction
- Waste of limited financial resources
- Loss of credibility
Quality Assurance

Quality Control
**QUALITY**: A measure of excellence or a state of being free from defects, deficiencies and significant variations.

**QUALITY ASSURANCE**: Obtaining confidence that, required quality of product or service is satisfactory for their intended use.

**QUALITY CONTROL**: Part of GMP concerned with sampling, testing and specifications.
Quality Culture

- Support for the Quality Organization
- Actions More Than Words
- Investment in Quality
- Quality Involved in Relevant Business Decisions
- The Quality of the Work You Accept Becomes the Organization’s Standard
- Organizational Structure: Assures that Quality is independent and not subordinate to other organizational unit
Quality Responsibility

Quality is the collective responsibility of every individual in an organization.

It is a well known belief that quality initiatives are successful only when it is driven from top management to the lower levels of management.
Quality must be Designed into a Product

Quality by design (QbD approach)

- Quality is not an add-on: it begins with research and development
- Product quality criteria must be established
- Detailed specifications provide quantitative parameters for measurement
- Written procedures document how quality is attained and maintained
- Continuous monitoring (sampling, testing) to confirm quality is being built-into product
Functions of QA in Pharmaceutical industry

To Ensure:

- Raw materials used in the manufacturing are approved and procured from approved vendor.
- All datas are recorded as per cGMP and is reviewed for accuracy and traceability.
- Procedures are in place for performing the activities, operating and calibrating the equipment.
- Quality is built up in the plant, process, product. That a Robust Quality system is in place.
- Trainings like induction, On job, Scheduled and after any changes are conducted to respective individuals on time.
Functions of QA in Pharmaceutical industry

- To prepare and approve Quality Policy, Quality Objectives, Quality Manual and Validation Master Plan.
- Periodic Monitoring of the Quality Objectives.
- Monitors all validation & stability activities are completed as per the schedule.
- Ensures that all changes impacting the product and the established systems are documented and reviewed to analyze the impact.
- Ensures that all deviations, OOS/OOT & Market complaints are logged, investigated to identify the root cause so as to take CAPA to prevent recurrence.
- Preparation of Annual product quality reports, trending of data, determining product and process performance.
- To arrange and conduct the self inspection, identify gaps and take CAPA.
- Review of related batch manufacturing records and QC testing data Prior to release of any batch.
Quality Control

Performs following activities:

**Routine:**
- RM & PM analysis
- Intermediate stage analysis
- Finished Products analysis
- Stability Studies

**Non Routine:**
- Calibration & Preventive maintenance of instruments
- Preparation of reference/ working standards
- Method development/ validation

Activities managed through:
- Instrumental Analysis
- Chemical Analysis (RM & FG)
- Microbiological Analysis
- Packaging Material Analysis
Testing Flow

RM/PM Testing

1. Raw Material
2. Packaging Materials
   - Receipt
   - Verification
   - Sampling
   - Under Test
   - Q.C. Testing
      - Approved
         - For Manufacturing
      - Rejected
         - Return to Supplier / Destruction

Finished Good Testing

1. Completion of Batch of Finished Products
   - Sampling by QA
   - Under Test
   - Q.C. Testing
     - Preparation of Report And Checking
        - Approved
           - For Distribution
        - Rejected
           - Destruction
Functions of QC in pharmaceutical industry:

- Preparation of specifications for testing of materials and products.
- Carrying out Sampling and testing of materials or products.
- Environment Monitoring
- Conducting stability studies.
- Investigating test failures such as OOS / OOT / OOAC / OOAL.
- Analytical method validation.
- Evaluation of complaint samples.

All the quality control activities are performed adherence to the GLP.
Quality Metrics -
A tool (ISPE: International Standards for Pharmaceutical Engineers) for continuous improvement in Quality

It is a measurement standard by which efficiency, performance, progress compliance or quality of a process, or product can be assessed.

1. KPI’s shall be identified based on impact on organization goals and quality.
2. Weightage to be provided for each KPI.
3. Scoring to be provided for each KPI based on actual performance.
4. Communication to top management.
5. Necessary developments to be made to improve the failed KPI

**e.g. of KPI’s** - Batch failures, Market complaints, deviations, Changes, OOS, Stability overdue, RM/PM/FG release time.
# Scope of QA / QC in pharmaceutical

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Criteria</th>
<th>Quality Assurance</th>
<th>Quality Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Focus</td>
<td>To prevent defects with a focus on the process.</td>
<td>To identify defects in the finished product.</td>
</tr>
<tr>
<td>2</td>
<td>Goal</td>
<td>To improve development and test processes so that defects do not arise.</td>
<td>To identify defects after a product is developed and before it's released.</td>
</tr>
<tr>
<td>3</td>
<td>How</td>
<td>Establish a good quality management system &amp; assessment of its adequacy with continuous monitoring.</td>
<td>Finding sources of quality problems to continually meet customer's requirement.</td>
</tr>
<tr>
<td>Sr. No.</td>
<td>Criteria</td>
<td>Quality Assurance</td>
<td>Quality Control</td>
</tr>
<tr>
<td>--------</td>
<td>--------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>4</td>
<td>What</td>
<td>Prevention of quality problems through planned and systematic activities.</td>
<td>Analytical techniques used to maintain the product quality and process.</td>
</tr>
<tr>
<td>5</td>
<td>Responsibility</td>
<td>Everyone on the team.</td>
<td>Of a specific team that tests the product for defects.</td>
</tr>
<tr>
<td>6</td>
<td>As a tool</td>
<td>QA is a managerial tool</td>
<td>QC is a corrective tool</td>
</tr>
</tbody>
</table>