Six System Inspection model

Quality Management System

- The Quality Management System is the foundation of the Six System Inspection Model.
- It ensures that all quality-related activities are properly planned, implemented, monitored, and continuously improved.
- The Quality Management System provides confidence that pharmaceutical products consistently meet quality standards and regulatory requirements.

Definition

- The Quality Management System is a formal system of policies, procedures, responsibilities, and resources established to ensure consistent product quality throughout the organization.

Objectives

- To maintain consistent product quality.
- To ensure compliance with cGMP requirements.
- To improve customer satisfaction.
- To identify and prevent quality problems.
- To promote continuous improvement.

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Major Components

1. **Quality Policy**
   - The organization should establish a written quality policy.
   - The quality policy should demonstrate management's commitment to quality.
2. **Documentation System**
   - Standard Operating Procedures (SOPs), batch records, specifications, and quality manuals should be properly prepared and maintained.
   - Documentation should provide complete traceability of manufacturing activities.
3. **Corrective and Preventive Action (CAPA)**
   - Deviations and quality problems should be investigated thoroughly.
   - Corrective actions should eliminate existing problems.
   - Preventive actions should reduce the possibility of future problems.
4. **Internal Audits**
   - Regular self-inspections should be conducted to evaluate compliance with quality standards.

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- Audit findings should be documented and corrected promptly.

5. Management Review

- Top management should periodically review the effectiveness of the Quality Management System.
- Improvement opportunities should be identified and implemented.

Importance

- Product quality remains consistent.
- Regulatory compliance is maintained.
- Manufacturing errors are minimized.
- Customer confidence is improved.

Production System

Basic Idea

- The Production System includes all manufacturing activities involved in producing pharmaceutical products.
- It ensures that products are manufactured according to approved procedures and quality standards.
- Proper control of production activities prevents contamination, mix-ups, and manufacturing errors.

Definition

- The Production System consists of all manufacturing operations, procedures, personnel, and controls involved in producing pharmaceutical products.

Objectives

- To manufacture products consistently.
- To prevent contamination.
- To ensure compliance with manufacturing procedures.
- To maintain product quality.

Major Components

1. Manufacturing Process

- Manufacturing should follow approved Standard Operating Procedures (SOPs).
- Every production step should be properly documented.

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2. In-Process Controls

- Quality checks should be performed during manufacturing.
- Critical process parameters should be continuously monitored.

3. Process Validation

- Manufacturing processes should be validated before routine production.
- Validation demonstrates that the process consistently produces quality products.

4. Cleaning Procedures

- Equipment and production areas should be cleaned according to approved procedures.
- Cleaning validation should confirm the removal of product residues and contaminants.

5. Batch Documentation

- Complete batch manufacturing records should be maintained.
- Records should accurately describe every manufacturing activity.

Importance

- Manufacturing becomes consistent and reliable.
- Product quality is maintained throughout production.
- Contamination risks are minimized.
- Regulatory requirements are fulfilled.

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Facility and Equipment System

Basic Idea

- The Facility and Equipment System ensures that buildings, utilities, and equipment are properly designed, installed, maintained, and operated.
- Proper facilities and equipment help maintain product quality and prevent contamination.

Definition

- The Facility and Equipment System includes all buildings, utilities, manufacturing equipment, maintenance activities, and environmental controls required for pharmaceutical production.

Objectives

- To provide suitable manufacturing facilities.
- To maintain equipment in good condition.
- To prevent contamination.
- To ensure reliable manufacturing operations.

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Major Components

A. Facility Design

- Manufacturing areas should be properly designed to prevent contamination.
- Different production areas should be separated when necessary.

B. Equipment Qualification

- Equipment should undergo Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).
- Qualification confirms that equipment performs as intended.

C. Calibration

- Measuring instruments should be calibrated regularly.
- Calibration ensures accurate and reliable measurements.

D. Preventive Maintenance

- Equipment should be inspected and maintained according to a planned schedule.
- Preventive maintenance reduces equipment failures.

E. Environmental Control

- Temperature, humidity, air pressure, and cleanliness should be continuously monitored.
- Controlled environmental conditions help maintain product quality.

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Importance

- Equipment operates efficiently.
- Manufacturing interruptions are reduced.
- Product contamination is prevented.
- Product quality remains consistent.

Laboratory Control System

Basic Idea

- The Laboratory Control System ensures that all laboratory activities are performed accurately and according to approved procedures.
- It includes testing of raw materials, in-process samples, finished products, and stability samples.
- Laboratory results help determine whether products meet quality specifications before release.

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Definition

- The Laboratory Control System consists of laboratory procedures, analytical methods, instruments, personnel, and documentation used to evaluate product quality.

Objectives

- To ensure accurate laboratory testing.
- To verify compliance with product specifications.
- To detect quality defects.
- To support product release decisions.

Major Components

1. Analytical Testing

- Raw materials, in-process materials, and finished products should be tested according to approved specifications.
- Validated analytical methods should be used.

2. Method Validation

- Analytical methods should be scientifically validated.
- Validation confirms that test methods produce accurate and reliable results.

3. Laboratory Equipment

- Laboratory instruments should be calibrated and maintained regularly.
- Equipment should function accurately before testing begins.

4. Sample Management

- Samples should be properly collected, labeled, stored, and documented.
- Sample integrity should be maintained throughout testing.

5. Documentation

- Laboratory records should accurately document all testing activities.
- Test results should be reviewed before product release.

Importance

- Laboratory results become reliable.
- Product quality is accurately evaluated.
- Defective products are prevented from reaching patients.
- Regulatory compliance is maintained.

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