

Auditing of Quality Assurance & engineering department

Quality Assurance Maintenance

Meaning of Quality Assurance Maintenance

- **Quality Assurance (QA)** maintenance refers to all ongoing activities performed by the QA department to ensure that quality systems are continuously functioning effectively.



- It includes maintaining procedures, records, systems, and controls required for compliance with cGMP.
- In **Audits and Regulatory Compliance**, QA maintenance ensures that the organization remains in a constant state of control and readiness for inspections.

Objectives of Maintenance QA

- To ensure continuous compliance with regulatory requirements.
- To maintain and improve quality systems.
- To ensure consistency in product quality.
- To detect and correct deviations in a timely manner.

Key Functions in QA Maintenance

1. Document Control and Management

- Preparation, review, approval, and revision of SOPs and documents.
- Ensuring only updated documents are in use.
- Proper archiving and retrieval of records.

2. Deviation Management

- Identification and documentation of deviations from standard procedures.
- Investigation of root causes.
- Implementation of corrective and preventive actions (CAPA).

3. Change Control System

- Managing changes in processes, equipment, materials, or documents.
- Ensuring changes do not negatively affect product quality.

4. CAPA (Corrective and Preventive Actions)

- Corrective action to fix existing problems.
- Preventive action to avoid future issues.

5. Internal Audits (Self-Inspection)

- Regular audits to ensure compliance with cGMP.
- Identification of deficiencies and follow-up actions.

6. Training Management

- Ensuring employees are trained on updated procedures.
- Maintaining training records.

7. Batch Record Review and Product Release

- QA reviews batch records before releasing products.
- Ensures all processes were followed correctly.

8. Handling Complaints and Recalls

- Investigation of product complaints.
- Management of product recall if required.

Audit Focus in QA Maintenance

- Completeness and accuracy of documentation.
- Effectiveness of deviation and CAPA systems.
- Control over changes and updates.
- Frequency and quality of internal audits.
- Training records and compliance.

Common Deficiencies in QA Maintenance

- Outdated or uncontrolled documents.
- Poor investigation of deviations.

- Ineffective CAPA implementation.
- Incomplete audit follow-up.

Importance in Regulatory Compliance

- QA maintenance is central to compliance.
- Ensures continuous improvement and control.
- Helps in successful regulatory inspections.

Auditing of Engineering Department (Critical Systems)

Meaning of Engineering Audit

- **Engineering audit focuses** on evaluating **critical utility systems** that support pharmaceutical manufacturing.
- These systems directly impact product quality, environmental control, and contamination prevention, especially in controlled and sterile areas.

Meaning of Critical Systems

- **Critical systems are essential support systems that:**
 - Maintain controlled environmental conditions
 - Preventing contamination and cross-contamination
 - Directly affect product quality and safety
- Failure of these systems can lead to serious quality issues and regulatory non-compliance.

Importance of Engineering Audit

- Ensures proper functioning of systems
- Preventing contamination and system failures
- Maintains controlled manufacturing environments
- Ensures compliance with regulatory standards

HVAC System (Heating, Ventilation, and Air Conditioning)

Meaning of HVAC

- **HVAC system controls:**
 - Temperature
 - Humidity
 - Air filtration

- Airflow and pressure differentials
- It is essential for maintaining **cleanroom conditions**.

Objectives of HVAC Audit

- Maintain clean and controlled environment
- Preventing contamination and cross-contamination

Key Audit Areas / Points

- **Proper design**, qualification, and validation of HVAC system
- Use and maintenance of HEPA filters
- **Monitoring of:**
 - Temperature and humidity
 - Air pressure differentials
- Calibration of sensors and instruments
- Preventive maintenance schedules
- Environmental monitoring records

Common Issues

- Poor air filtration
- Improper pressure differentials
- Lack of maintenance or calibration

Water System

Meaning

- System used to **generate, store, and distribute purified water** for manufacturing and cleaning.

Key Audit Areas / Points

- Validation of water generation systems (RO, deionization, etc.)
- Monitoring of chemical and microbiological quality
- Proper storage tanks and distribution pipelines
- Routine sanitization and maintenance
- Documentation of testing and maintenance records

Common Issues

- Microbial contamination



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