

# GxP Pharmaceutical Audit Checklist

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## Scope & Planning

Review of audit scope, objectives, and planning activities.

### Audit Start Date

Enter date...

### Audit End Date

Enter date...



### Audit Team Size

Enter a number...

### Audit Type

- Routine
- For Cause
- Follow-up

### Audit Objectives & Scope Description

Write something...

### Areas to be Audited (Select all that apply)

- Manufacturing
- Quality Control
- Warehouse
- Document Control

### Auditee Contact Person

Write something...

# Personnel & Training

Assessment of personnel qualifications, training records, and competency.

## Employee ID

## Job Title

- Quality Assurance
- Manufacturing
- Laboratory
- Maintenance
- Other

## Date of Last Training (GxP)

## Training Status

- Completed
- In Progress
- Not Started

### Training Summary/Description

Write something...

### Training Certificates/Records

 Upload File

### Qualified for Critical Roles?

- Yes
- No
- N/A

## Standard Operating Procedures (SOPs)

Verification of SOP existence, review, approval, and adherence.

### SOP Review Frequency

- Annual
- Bi-Annual
- As Needed

### Last SOP Review Date

Enter date...

### SOP Approval Status

- Approved
- Pending Approval
- Rejected

### Comments Regarding SOP Review (if applicable)

Write something...

### Reviewer Signature

### SOP Revision Number

Enter a number...

### Upload of Updated SOP Document

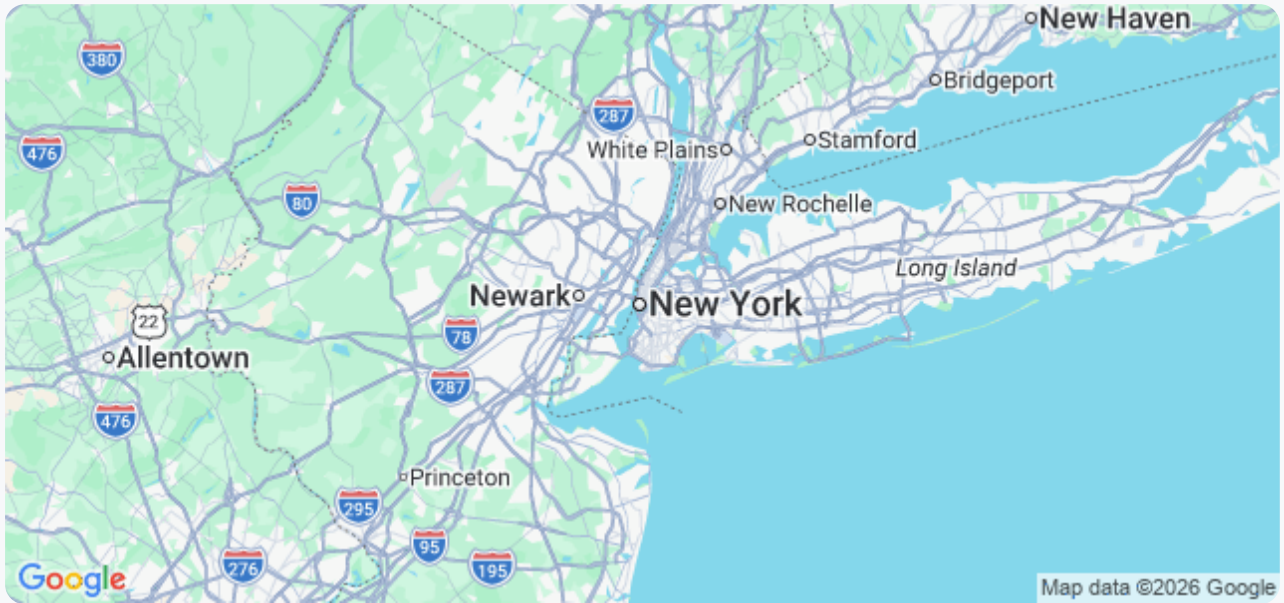
 Upload File

# Facilities & Equipment

Evaluation of facility design, maintenance, calibration, and equipment suitability.

## Area/Room Audited

 [Set My Current Location](#)



## Equipment Serial Number

Enter a number...

## Last Calibration Date

Enter date...

### Temperature at Time of Audit

### Temperature Range (validated)

### Equipment Status

- Operational
- Out of Service
- Under Maintenance

### Observations/Comments on Facility/Equipment Condition

### Supporting Documentation (e.g., Calibration Certificates)

 Upload File

## Materials Management

Assessment of raw material sourcing, testing, storage, and handling.

### Batch Number

### Date of Receipt

Enter date...

### Quantity Received

Enter a number...

### Supplier

- Supplier A
- Supplier B
- Supplier C

### Supplier CoA Review Comments

Write something...

### Material Status Upon Receipt

- Acceptable
- Quarantine
- Rejected

### Quarantine Reason (if applicable)

Write something...

### Supplier CoA

 Upload File

## Manufacturing Processes

Review of manufacturing steps, in-process controls, and documentation.

### Batch Number

Enter a number...

### Start Date of Manufacturing

Enter date...

### Start Time of Manufacturing

Enter time...

### Manufacturing Process Narrative - Briefly describe deviations from SOP

Write something...

### Equipment Used (Select all that apply)

- Mixer
- Granulator
- Tablet Press
- Capsule Filling Machine
- Dryer
- Coater

### Weight of Material Added (kg)

Enter a number...

### Appearance of Product (Select one)

- Correct
- Slightly Off
- Significant Deviation

### Operator Signature

# Laboratory Controls

Evaluation of testing methods, data integrity, and analytical equipment.

## Equipment Calibration Frequency (Months)

Enter a number...

## Last Calibration Date

Enter date...


## Summary of Calibration Results/Deviations

Write something...

## Method Validation Status

- Validated
- Not Validated
- Validation Expiration Approaching

## Method Validation Report (if applicable)

 Upload File

### Number of Out-of-Specification (OOS) Results

Enter a number...

### Description of OOS Investigation (if applicable)

Write something...

### Data Integrity Controls in Place?

- Yes
- No
- Not Applicable

## Documentation & Records

Verification of record-keeping practices, data integrity, and traceability.

### Document Number

Write something...

### Document Creation Date

Enter date...

### Document Review Date

Enter date...

### Document Status (Approved/Revoked/Obsolete)

Approved

Revoked

Obsolete

### Document Revision History (brief summary)

Write something...

### Upload Document (PDF/Word)

 Upload File

### Number of copies distributed

Enter a number...

### Reviewer Signature

# Change Control

Assessment of change management processes and impact assessments.

## Change Control Number

Enter a number...

## Date of Change Request

Enter date...

## Description of Proposed Change

Write something...

## Change Category (e.g., Equipment, Process, SOP)

- Equipment
- Process
- SOP
- Material
- Facility

### Rationale for Change

Write something...

### Estimated Implementation Time (Days)

Enter a number...

### Risk Assessment Level (Low, Medium, High)

- Low
- Medium
- High

### Requestor Signature

## Deviations & CAPA

Review of deviation management, corrective and preventive actions.

### Deviation Number

Enter a number...

### Date of Deviation

Enter date...

### Detailed Description of Deviation

Write something...

### Deviation Severity (e.g., Minor, Moderate, Major)

- Minor
- Moderate
- Major

### Root Cause Analysis

Write something...

### Corrective Action Plan

Write something...

### Corrective Action Due Date

Enter date...

### Effectiveness Check / Verification Results

Write something...

### CAPA Status

- Open
- In Progress
- Closed

### CAPA Reviewer Signature

## Complaints & Recalls

Evaluation of complaint handling and recall procedures.

### Complaint/Recall Number

Enter a number...

### Date of Complaint/Recall Initiation

Enter date...

### Detailed Description of Complaint/Recall Event

Write something...

### Product Affected

- Drug Product
- Active Pharmaceutical Ingredient (API)
- Excipient

### Severity Level

- Critical
- Serious
- Moderate
- Minor

### Root Cause Categories (if known)

- Equipment Failure
- Process Deviation
- Personnel Error
- Supplier Issue
- Packaging Defect

### Supporting Documentation (e.g., batch records, lab reports)

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### Target Completion Date for Corrective Action

Enter date...

## Vendor Management

Assessment of vendor qualification and oversight.

### Vendor Risk Level

- Low
- Medium
- High

### Vendor Qualification Date

Enter date...

### Vendor Qualification Rationale

Write something...

### Vendor Audit Report

 Upload File

### Number of Audits Conducted

Enter a number...

### Vendor Status

- Approved
- Suspended
- Rejected

### Summary of Last Audit Findings

Write something...

## Data Integrity

Verification of data integrity controls (ALCOA principles).

### ALCOA-C Principle Compliance: Source

- Documented
- Electronic System
- Both

### Audit Trail Enabled?

- Yes
- No
- N/A

### Number of Data Integrity Events Identified (if any)

Enter a number...

### Description of Identified Data Integrity Risks or Concerns

Write something...

### Data Integrity Controls Implemented (Select all that apply)

- Access Controls
- Audit Trails
- Data Encryption
- Change Control
- Training Records
- Validation of Computerized Systems

### Last Data Integrity Training Completion Date

Enter date...

### Are User Access Rights Reviewed Periodically?

- Yes
- No
- N/A

## Closing & Reporting

Review of audit findings, report preparation, and follow-up actions.

### Audit Completion Date

Enter date...

### Audit Completion Time

Enter time...

### Summary of Key Findings

Write something...

### Number of Major Observations

Enter a number...

### Number of Minor Observations

Enter a number...

### Overall Audit Rating

- Acceptable
- Requires Improvement
- Unsatisfactory

### Lead Auditor Signature

### Supporting Documentation (e.g., Photo Evidence)

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