



GxP Pharmaceutical Audit Checklist

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

Enter a number...

Job Title

- ☐ Quality Assurance
- ☐ Manufacturing
- ☐ Laboratory
- ☐ Maintenance
- ☐ Other

Date of Last Training (GxP)

Enter date...

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

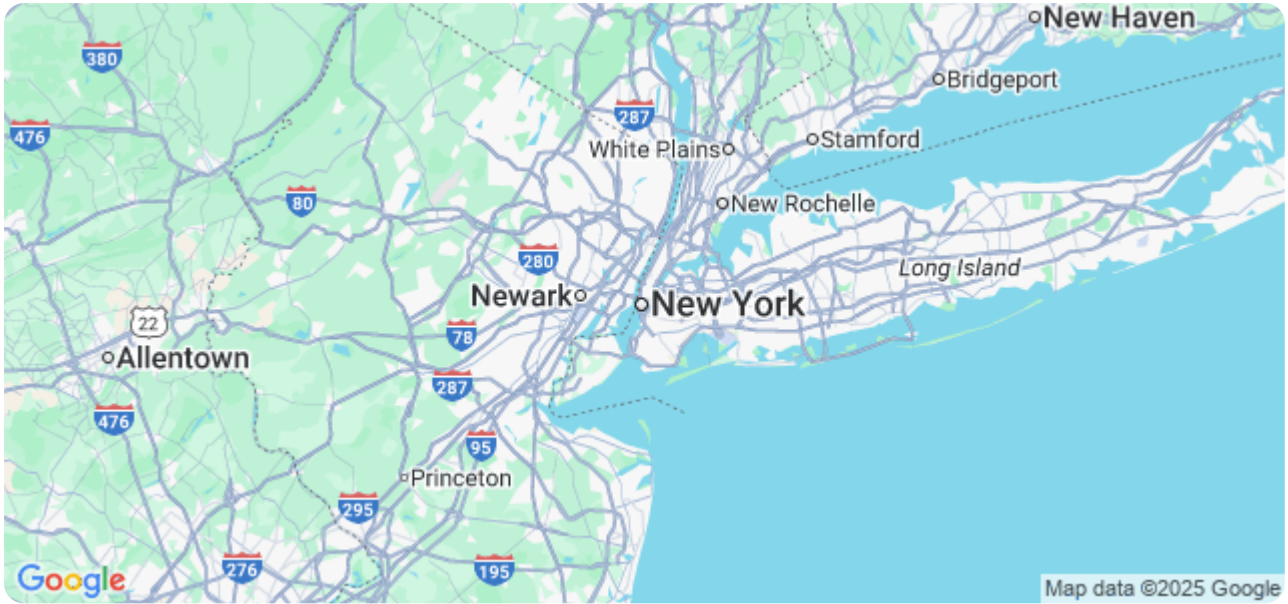
 Upload File

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)

Enter a number...

Equipment Status

- ☐ Operational
- ☐ Out of Service
- ☐ Under Maintenance

Observations/Comments on Facility/Equipment Condition

Write something...

Supporting Documentation (e.g., Calibration Certificates)

 Upload File

Materials Management

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

Batch Number

Enter a 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

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)

Last Calibration Date

Summary of Calibration Results/Deviations

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

Date of Deviation

Detailed Description of Deviation

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)

 Upload File

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

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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