ChecklistGuro

GxP Pharmaceutical Audit Checklist

Show only Checklist

Display Style
Default

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

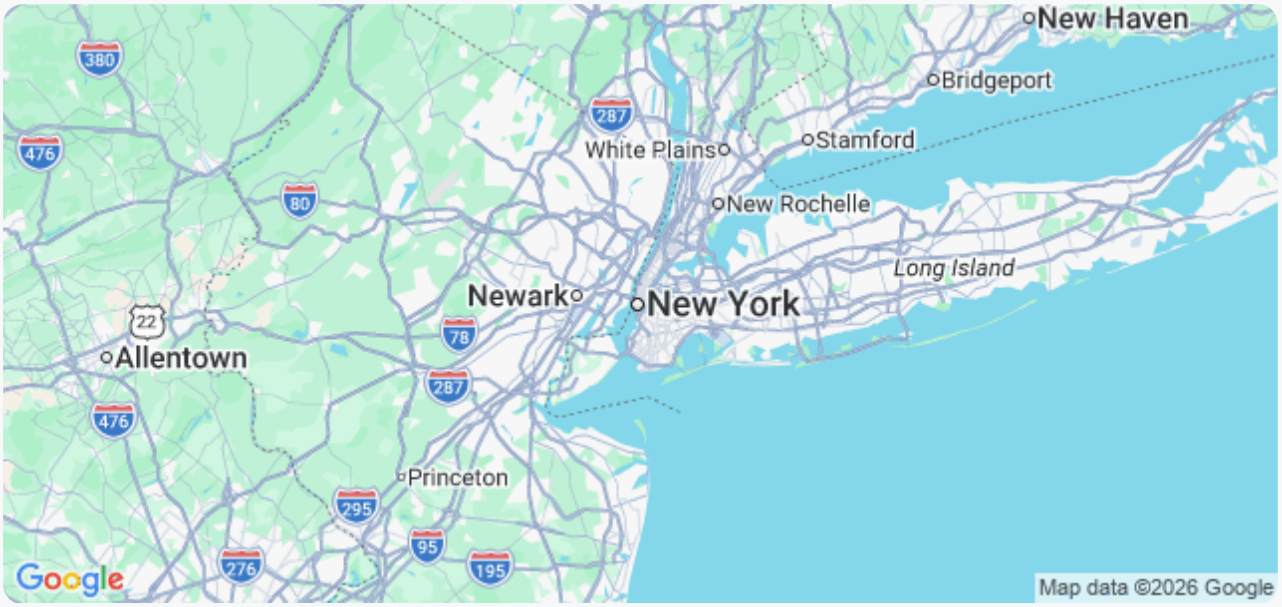
Upload File

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

Enter time...

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

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)

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

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)

Upload File