ChecklistGuro

Good Laboratory Practice (GLP) Checklist

This Template was installed **0** times.

Personnel & Training

Ensures qualified personnel are available and adequately trained for all manufacturing activities.

Number of Trained Personnel

Enter a number...

Training Records Accessible?

- [ ] Yes
- [ ] No

Last Training Refresher Date (Manufacturing Personnel)

Enter date...

Briefly describe the training program content (Manufacturing Personnel)

Write something...

Training Topics Covered (Select all that apply)

- [ ] SOPs
- [ ] Safety Procedures
- [ ] Equipment Operation
- [ ] Data Integrity
- [ ] GLP Principles
- [ ] Quality Control

Is there a documented training matrix?

- [ ] Yes
- [ ] No

Description of procedures for addressing performance deficiencies identified during training or manufacturing.

Write something...

Facilities & Equipment

Covers the suitability, maintenance, and calibration of facilities and equipment used in the manufacturing process.

Room Temperature (°C)

Enter a number...

Humidity (%)

Cleaning Validation Status

- [ ] Validated
- [ ] Not Validated
- [ ] Revalidation Needed

Last Calibration Date - Critical Equipment (e.g., Balances, pH Meters)

Enter date...

Equipment Maintenance Schedule Adherence

- [ ] Compliant
- [ ] Minor Deviation
- [ ] Major Deviation

Description of Any Observed Environmental Issues (e.g., leaks, pests)

Write something...

Calibration Certificates (Upload)

Upload File

HVAC System Functionality

- [ ] Fully Functional
- [ ] Minor Issue
- [ ] Major Issue

Materials Management

Addresses the procurement, storage, handling, and traceability of raw materials, intermediates, and finished products.

Batch Number Verification

Enter a number...

Material Supplier Qualification Status

- [ ] Approved
- [ ] Pending Approval
- [ ] Not Approved

Date of Material Receipt

Enter date...

Material Receipt Comments (e.g., condition upon arrival)

Write something...

Quantity Received (per unit)

Enter a number...

Material Storage Condition

- [ ] Controlled Temperature

Storage Location Notes

Write something...

Certificate of Analysis (CoA)

Upload File

Quarantine Status

- [ ] Quarantined
- [ ] Released

Manufacturing Procedures (SOPs)

Focuses on documented procedures ensuring consistency and quality in the manufacturing process.

SOP Exists for Each Manufacturing Step?

Write something...

Are SOPs Regularly Reviewed and Updated?

Upload File

SOP Approval Process Defined?

- [ ] Yes
- [ ] No
- [ ] Not Applicable

SOP Revision Number

Enter a number...

Date of Last SOP Review

Enter date...

Departments Involved in SOP Review/Approval

- [ ] Manufacturing
- [ ] Quality Assurance
- [ ] Engineering
- [ ] Regulatory Affairs

Brief Description of SOP Change Control Process Related to Manufacturing Procedures

Write something...

Documentation & Record Keeping

Covers the proper recording, storage, and security of all manufacturing records

Batch Manufacturing Record (BMR) Completeness

Write something...

Date of Record Creation

Enter date...

Time of Record Creation

Batch Number

Enter a number...

Equipment Log Entries Description

Write something...

Supporting Documents (e.g., Chromatograms, Test Results)

Upload File

Record Review Status (Approved/Rejected)

- [ ] Approved
- [ ] Rejected

Reviewer Signature

Corrections/Amendments Description (if any)

Write something...

Date of Record Review

Enter date...

Quality Control & Testing

Ensures adequate quality control procedures and testing are in place to verify product quality.

Batch Number Verified?

Enter a number...

Analytical Method Used (per SOP)?

- [ ] Method A
- [ ] Method B
- [ ] Method C
- [ ] Other (Specify)

Analytical Results Summary (briefly describe)

Write something...

Temperature during Testing (deg C)

Enter a number...

Date of Testing

Enter date...

Tests Performed (check all that apply)

- [ ] Appearance
- [ ] Assay
- [ ] Identity
- [ ] Purity
- [ ] Moisture Content
- [ ] Other (Specify)

Attach Analytical Certificates/Reports

Upload File

Deviations & Investigations

Addresses the process for identifying, documenting, investigating, and resolving

Date of Deviation

Enter date...

Time of Deviation

Detailed Description of Deviation

Write something...

Root Cause Analysis (RCA)

Write something...

Potential Contributing Factors

- [ ] Equipment Failure
- [ ] Human Error
- [ ] Material Issue
- [ ] Procedure Inadequacy
- [ ] Other (Specify in LONG_TEXT)

Corrective Action Plan

Write something...

Number of Batches Affected (if applicable)

Enter a number...

Severity of Deviation

- [ ] Minor
- [ ] Moderate
- [ ] Major

Signature of Investigator

Date Corrective Action Implemented

Enter date...

Change Control

Covers the process for managing and documenting changes to manufacturing processes, equipment, or materials.

Description of Proposed Change

Write something...

Reason for Change Request

Estimated Impact on Production Timeline (Days)

Enter a number...

Affected Areas/Departments

- [ ] Manufacturing
- [ ] Quality Control
- [ ] Engineering
- [ ] Regulatory Affairs
- [ ] Supply Chain

Date of Change Request

Enter date...

Change Priority (High, Medium, Low)

- [ ] High
- [ ] Medium
- [ ] Low

Supporting Documentation (e.g., Drawings, Specifications)

Upload File

Change Status (Submitted, In Review, Approved, Rejected, Implemented)

- [ ] Submitted
- [ ] In Review
- [ ] Approved
- [ ] Rejected
- [ ] Implemented

Requestor Signature

Equipment Qualification & Validation

Verification and documentation that equipment and processes perform as expected.

Date of Initial Qualification

Enter date...

Equipment Serial Number

Enter a number...

Description of Qualification Activities Performed

Write something...

Acceptance Criteria Threshold (e.g., Temperature Range)

Qualification Status

- [ ] Passed
- [ ] Failed
- [ ] Pending
- [ ] N/A

Qualification Report (PDF/DOCX)

Upload File

Date of Last Requalification/Verification

Enter date...

Details of any Deviations found during Qualification and Corrective Actions Taken

Write something...

Equipment Type

- [ ] Manufacturing Equipment
- [ ] Cleaning Equipment
- [ ] Analytical Equipment
- [ ] Other

Signature of Person Performing Qualification

Process Validation

Demonstration that a manufacturing process consistently produces products meeting predetermined specifications.

Validation Plan Summary: Briefly describe the overall validation plan for the manufacturing process.

Write something...

Number of Validation Batches: Specify the number of batches used for process validation.

Enter a number...

Start Date of Validation Campaign: Record the commencement date of the validation process.

Enter date...

Completion Date of Validation Campaign: Document the end date of the validation process.

Enter date...

Acceptance Criteria for Critical Process Parameters (CPPs): Specify the acceptable range for each CPP.

Enter a number...

Validation Status: Select the current validation status (e.g., Planned, In Progress, Completed, Failed).

- [ ] Planned
- [ ] In Progress
- [ ] Completed
- [ ] Failed

Attachment: Raw data, validation reports, statistical analysis results

Upload File

Summary of Validation Results & Conclusion: Detailed summary of the validation findings and the overall conclusion regarding process validation.

Write something...

Validation Team Leader Signature

Related Checklist Templates

- Confined Space Entry
- Management Of Change (MOC)
- Personal Protective Equipment (PPE)
- A3 Problem Solving Report

- Ergonomic Assessment Checklist
- First Article Inspection (FAI) Checklist
- Lockout/Tagout (LOTO) Checklist
- Maintenance Pre-Startup Safety Review (PSSR)
- FMEA (Failure Mode And Effects Analysis) Checklist
- Calibration Checklist

WE CAN DO IT TOGETHER

NEED HELP WITH CHECKLISTS?

Have a question? We're here to help. Please submit your inquiry, and we'll respond promptly.

Email Address

Phone Number

How can we help?

SEND YOUR REQUEST