ChecklistGuro

Good Manufacturing Practices (GMP) Checklist

Personnel & Training

Focuses on the qualifications, training, and hygiene of personnel involved in the manufacturing process.

Number of Qualified Personnel

Enter a number...

Training Records Maintained?

- [ ] Yes
- [ ] No
- [ ] N/A

Last GMP Training Completion Date (Employee 1)

Enter date...

Brief Description of Training Program Content

Write something...

Personnel Hygiene Practices Observed?

- [ ] Yes
- [ ] No
- [ ] N/A

Personnel Training Records (Sample)

Upload File

Specific Training Areas Covered (Select All That Apply)

- [ ] Data Integrity
- [ ] Equipment Operation
- [ ] Personal Hygiene
- [ ] Process Validation
- [ ] Good Documentation Practices

Name of Designated Training Coordinator

Write something...

Premises & Equipment

Addresses the cleanliness, maintenance, and suitability of the manufacturing facility and equipment.

Ambient Temperature (Manufacturing Area)

Enter a number...

Relative Humidity (Manufacturing Area)

Enter a number...

Description of any pest control measures taken

Write something...

Floor Material Adequacy

- [ ] Appropriate and Cleanable
- [ ] Needs Improvement
- [ ] Unacceptable

Lighting Adequacy

- [ ] Adequate for Operations
- [ ] Insufficient
- [ ] Needs Adjustment

Photographs of Equipment and Facility

Upload File

Last Equipment Cleaning Date

Enter date...

Description of any identified deficiencies

Write something...

Documentation & Records

Covers the systems and procedures for documenting all aspects of the manufacturing process.

Document Creation Date

Enter date...

Document Revision Number

Enter a number...

Document Purpose and Scope

Write something...

SOP Document (e.g., Manufacturing Instructions)

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Document Status (Approved/Reviewed/Obsolete)

- [ ] Approved
- [ ] Reviewed
- [ ] Obsolete

Document Review Date

Enter date...

Prepared By (Name & Position)

Write something...

Signature of Document Author

Raw Materials & Components

Covers receipt, storage, testing, and handling of raw materials and components.

Batch Number of Received Material

Enter a number...

Date of Receipt

Enter date...

Supplier Approval Status

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

Quantity Received

Enter a number...

Quantity Accepted

Enter a number...

Remarks/Observations during Receipt

Write something...

Certificate of Analysis (CoA) Received?

- [ ] Yes
- [ ] No

CoA File Upload (if applicable)

Upload File

Material Quarantine Status

- [ ] Quarantined
- [ ] Released

Manufacturing Process Controls

Details procedures to ensure consistent production and quality of the product.

Batch Size Confirmed?

Enter a number...

Process Step Adherence

- [ ] Fully Adhered
- [ ] Minor Deviation
- [ ] Significant Deviation

Process Parameter Monitoring Details

Write something...

Temperature During Reaction (ºC)

Enter a number...

Reaction Completion Time

Any Process Anomalies Observed?

Write something...

In-Process Testing Conducted?

- [ ] Yes
- [ ] No

In-Process Testing Results (if applicable)

Upload File

Packaging & Labeling

Covers the processes and controls related to packaging and labeling of the manufactured product.

Packaging Material Approved?

- [ ] Yes
- [ ] No
- [ ] N/A

Packaging Material Specification Number:

Write something...

Number of Packaging Components Verified:

Enter a number...

Details of any discrepancies found in packaging:

Write something...

Packaging Label Approval Document:

Upload File

Label Information Verified against Master Record?

- [ ] Yes
- [ ] No
- [ ] N/A

Label Elements Verified (Check all that apply):

- [ ] Product Name
- [ ] Batch Number
- [ ] Expiry Date
- [ ] Dosage/Strength
- [ ] Warnings
- [ ] Storage Conditions
- [ ] Manufacturer Information

Label Sequence Number:

Write something...

Cleaning & Sanitation

Focuses on procedures to maintain cleanliness and prevent contamination throughout the facility.

Cleaning Procedure Documentation

Write something...

Cleaning Agents Used (Specify all)

- [ ] Detergent
- [ ] Sanitizer (Specify type: _____)
- [ ] Disinfectant (Specify type: _____)
- [ ] Other (Specify: _____)

Concentration of Cleaning Agents (%, ppm, etc.)

Enter a number...

Date of Last Cleaning of Equipment/Area [Equipment ID/Area Name]

Enter date...

Details of any unusual cleaning procedures required for specific equipment/areas.

Write something...

Cleaning Validation Status (For Critical Equipment/Processes)

- [ ] Validated
- [ ] Not Validated
- [ ] Validation in Progress

Attach Cleaning Logs for Recent Cleaning Cycle

Upload File

Signature of Person Performing Cleaning Verification

Maintenance & Calibration

Addresses the maintenance and calibration of equipment and instruments.

Last Calibration Date - Equipment X

Enter date...

Calibration Result - Equipment X

Enter a number...

Tolerance Limit - Equipment X

Enter a number...

Calibration Standard Used

- [ ] NIST traceable
- [ ] In-house Standard
- [ ] Other (specify in LONG_TEXT)

Details of Calibration (if applicable)

Write something...

Calibration Status

- [ ] In Tolerance
- [ ] Out of Tolerance
- [ ] Requires Adjustment

Calibration Certificate

Upload File

Next Calibration Due Date - Equipment X

Enter date...

Deviations & Corrective Actions

Covers the process for identifying, documenting, and resolving deviations from established procedures.

Detailed Description of Deviation

Write something...

Date of Deviation Occurrence

Enter date...

Time of Deviation Occurrence

Quantity/Volume Affected (if applicable)

Enter a number...

Severity Level (e.g., Minor, Major, Critical)

- [ ] Minor
- [ ] Major
- [ ] Critical

Root Cause Analysis - Detailed Explanation

Write something...

Corrective Action Plan - Steps to be taken

Write something...

Planned Completion Date of Corrective Action

Enter date...

Verification Method (How was effectiveness confirmed?)

- [ ] Review of Records
- [ ] Re-testing
- [ ] Inspection
- [ ] Other

Signature of Person Implementing Corrective Action

Change Control

Addresses procedures for managing and documenting changes to manufacturing processes, equipment, or materials.

Description of Proposed Change

Write something...

Rationale for Change (Justification)

Write something...

Type of Change

- [ ] Minor
- [ ] Major
- [ ] Technical
- [ ] Personnel
- [ ] Equipment

Estimated Impact on Production (e.g., %)

Enter a number...

Proposed Implementation Date

Enter date...

Supporting Documentation (e.g., Drawings, SOP revisions)

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Affected Areas/Departments

- [ ] Manufacturing
- [ ] Quality Control
- [ ] Engineering
- [ ] Maintenance

Risk Assessment Summary

Write something...

Change Control Status

- [ ] Proposed
- [ ] Under Review
- [ ] Approved
- [ ] Rejected
- [ ] Implemented

Authorized Approver Signature