ChecklistGuro

Pharmaceutical Process Validation Checklist Template

Protocol Development

Review of the validation protocol, including objectives, scope, critical process parameters, acceptance criteria, and equipment/material list.

Protocol Objective(s)

Write something...

Batch Size (Proposed)

Enter a number...

Validation Type (e.g., Prospective, Concurrent, Retrospective)

- [ ] Prospective
- [ ] Concurrent
- [ ] Retrospective

Protocol Start Date (Planned)

Enter date...

Critical Process Parameters (CPPs)

- [ ] Temperature
- [ ] Pressure
- [ ] pH
- [ ] Mixing Speed
- [ ] Humidity
- [ ] Time

Initial Process Flow Diagram

Upload File

Process Understanding & Risk Assessment

Documentation of process knowledge, criticality assessment, and risk mitigation strategies.

Detailed Process Description

Write something...

Critical Process Parameter (CPP) - Upper Limit

Enter a number...

Critical Process Parameter (CPP) - Lower Limit

Enter a number...

Potential Failure Mode

- [ ] Equipment Malfunction
- [ ] Material Variation
- [ ] Operator Error
- [ ] Environmental Factors

Risk Mitigation Strategy

Write something...

Risk Score (Severity x Probability)

Enter a number...

Factors Influencing Risk

- [ ] Raw Material Quality
- [ ] Equipment Calibration
- [ ] Operator Training
- [ ] Environment Control

Equipment Qualification

Verification that critical equipment performs as intended under defined operating conditions. (IQ, OQ, PQ)

Equipment Serial Number

Enter a number...

Installation Date

Enter date...

Equipment Description & Specifications

Write something...

Qualification Phase (IQ, OQ, PQ)

- [ ] Installation Qualification (IQ)
- [ ] Operational Qualification (OQ)
- [ ] Performance Qualification (PQ)

Temperature Setpoint (°C)

Enter a number...

Temperature Recorded (°C)

Enter a number...

Duration of Stability Test (hours)

Qualified By

Material Qualification

Confirmation of material suitability and consistency for process execution.

Material Name

Write something...

Lot Number

Enter a number...

Receipt Date

Enter date...

Supplier

- [ ] Supplier A
- [ ] Supplier B
- [ ] Supplier C

Purity (%)

Enter a number...

Supplier CoA Review Comments

Write something...

CoA Document

Upload File

Material Status

- [ ] Approved
- [ ] Pending Review
- [ ] Rejected

Process Parameter Monitoring

Tracking and documentation of critical process parameters during validation runs.

Temperature (Run 1)

Enter a number...

Temperature (Run 1) - Min

Enter a number...

Temperature (Run 1) - Max

Enter a number...

Pressure (Run 1)

Enter a number...

Humidity (Run 1)

Enter a number...

Date of Reading (Run 1)

Enter date...

Time of Reading (Run 1)

Reading Status (Run 1)

- [ ] Within Specification
- [ ] Out of Specification
- [ ] Unverified

Sampling & Testing

Detailed plan for representative sampling and testing to demonstrate process capability.

Sample Size (n)

Enter a number...

Sampling Method

- [ ] Random Sampling
- [ ] Stratified Sampling
- [ ] Systematic Sampling

Sampling Date

Enter date...

Sampling Time

Test Method (e.g., USP)

- [ ] USP <1>
- [ ] USP <2>
- [ ] In-house Method

Result 1 (Numeric)

Enter a number...

Result 2 (Numeric)

Enter a number...

Test Comments/Observations

Write something...

Data Analysis & Evaluation

Assessment of validation data against pre-defined acceptance criteria and statistical analysis.

Batch Size

Enter a number...

Number of Validation Batches

Enter a number...

Acceptance Criteria Threshold (e.g., % Deviation)

Enter a number...

Statistical Method Used (e.g., ANOVA, t-test)

- [ ] ANOVA
- [ ] t-test
- [ ] Regression Analysis
- [ ] Other

Summary of Statistical Analysis Results

Write something...

Process Capability (Cp/Cpk)

- [ ] Cp >= 1.33
- [ ] Cpk >= 1.33
- [ ] Other

Justification for Acceptance/Rejection of Batch

Write something...

Deviation Management

Documentation and investigation of any deviations occurring during the validation process.

Deviation Description

Write something...

Date of Deviation

Enter date...

Time of Deviation

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

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

Batch Number Affected (if applicable)

Enter a number...

Affected Area(s) (e.g., Manufacturing, QC, Packaging)

- [ ] Manufacturing
- [ ] QC
- [ ] Packaging
- [ ] Warehouse
- [ ] Other

Root Cause Analysis

Write something...

Corrective Action Plan

Write something...

Corrective Action Completion Date

Enter date...

Reporting & Documentation

Compilation of all validation activities, results, and conclusions in a comprehensive final report.

Executive Summary of Validation Results

Write something...

Complete Validation Protocol Document

Upload File

Number of Validation Batches Executed

Enter a number...

Summary of Deviations and Corrective Actions

Write something...

Report Completion Date

Enter date...

Validation Manager Signature

Detailed Statistical Analysis Results

Write something...

Change Control & Continuous Improvement

Plan for managing changes to the validated process and mechanisms for continuous improvement based on validation findings.

Date of Change Request

Enter date...

Description of Change Request

Write something...

Change Category (e.g., Equipment, Process, Material)

- [ ] Equipment
- [ ] Process
- [ ] Material
- [ ] Personnel
- [ ] Other

Estimated Impact Score (1-5, 5 being highest impact)

Enter a number...

Affected Areas/Departments

- [ ] Manufacturing
- [ ] Quality Assurance
- [ ] Engineering
- [ ] Validation
- [ ] Supply Chain

Change Control Number

Write something...

Implementation Date

Enter date...