



# Pharmaceutical Continuous Improvement Checklist

## Data Collection & Analysis

Focuses on gathering relevant data, identifying trends, and analyzing performance metrics related to pharmaceutical processes.

**Batch Yield (%)**

Enter a number...

**Process Cycle Time (minutes)**

Enter a number...

**Equipment Status (Operational/Downtime/Maintenance)**

☐ Operational

☐ Downtime

☐ Maintenance

**Date of Data Collection**

Enter date...

### Rejection Rate (%)

Enter a number...

### Observations / Notes

Write something...

## Process Mapping & Identification of Waste

Visual representation of current processes to identify inefficiencies, bottlenecks, and areas of potential waste (time, resources, materials).

### Current Process Description

Write something...

### Types of Waste Identified (TIMWOODS)

- ☐ Transportation
- ☐ Inventory
- ☐ Motion
- ☐ Waiting
- ☐ Overproduction
- ☐ Over-processing
- ☐ Defects
- ☐ Skills (Underutilized)

### Cycle Time (Current)

Enter a number...

### Lead Time (Current)

Enter a number...

### Bottleneck(s) Identified

Write something...

### Description of Waste & Impact

Write something...

### Mapping Technique Used (e.g., Value Stream Mapping)

- ☐ Value Stream Mapping
- ☐ Swimlane Diagram
- ☐ Process Flowchart
- ☐ SIPOC

### Process Map Image/Document

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## Root Cause Analysis

Investigating identified problems to determine the underlying reasons and prevent recurrence.

### **Describe the Problem/Event**

Write something...

### **Initial Hypothesis for Root Cause(s)**

- ☐ Equipment Failure
- ☐ Process Deviation
- ☐ Human Error
- ☐ Material Issue
- ☐ Documentation Error
- ☐ Other (Specify in Long Text)

### **Describe Investigation Methods Used (e.g., 5 Whys, Fishbone Diagram)**

Write something...

### **Number of 'Whys' Applied (if using 5 Whys)**

Enter a number...

### **Detailed Description of Root Cause(s) Determined**

Write something...

### Contributing Factors (Select all that apply)

- ☐ Lack of Training
- ☐ Inadequate Supervision
- ☐ Poor Communication
- ☐ Insufficient Resources
- ☐ Design Flaw
- ☐ Other (Specify in Long Text)

### Date of Root Cause Determination

Enter date...

### Signature of Investigator

## Solution Development & Implementation

Brainstorming and implementing solutions to address identified root causes. Includes plan development, resource allocation, and timelines.

### Detailed Description of Proposed Solution

Write something...

### Estimated Cost of Implementation (USD)

Enter a number...

### Planned Start Date of Implementation

Enter date...

### Estimated Completion Date of Implementation

Enter date...

### Implementation Approach (e.g., Phased, Full Rollout)

- ☐ Phased Rollout
- ☐ Full Rollout
- ☐ Pilot Program

### Resources Required (Select all that apply)

- ☐ Personnel
- ☐ Equipment
- ☐ Software
- ☐ Budget

### Approving Manager Signature

## Standard Operating Procedure (SOP) Updates

Ensuring SOPs accurately reflect improved processes and are readily accessible to relevant personnel.

### SOP Revision Category

- ☐ Corrective Action
- ☐ Preventative Action
- ☐ Process Improvement
- ☐ Regulatory Requirement

### Summary of Changes

Write something...

### Previous SOP Version (for comparison)

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### Revised SOP Document

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### SOP Review Date

Enter date...

### Approval Status

- ☐ Draft
- ☐ Pending Review
- ☐ Approved
- ☐ Rejected

**Reviewer Signature**

## Training and Communication

Training employees on revised processes and communicating changes effectively.

**Training Program Description**

Write something...

**Training Delivery Method**

☐ Instructor-Led

☐ Online

☐ Blended

**Training Completion Date**

Enter date...

**Number of Employees Trained**

Enter a number...



### Topics Covered in Training

- ☐ SOP Updates
- ☐ New Equipment
- ☐ Regulatory Changes
- ☐ Process Improvements

### Training Materials (e.g., presentations, videos)

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### Employee Acknowledgement of Training

## Monitoring and Measurement

Tracking key performance indicators (KPIs) to assess the effectiveness of implemented improvements.

### Cycle Time Reduction (%)

### Defect Rate (per batch)

### Equipment Uptime (%)

### Overall Effectiveness Rating (Scale of 1-5)

- ☐ 1 - Poor
- ☐ 2 - Fair
- ☐ 3 - Average
- ☐ 4 - Good
- ☐ 5 - Excellent

### Date of Measurement

Enter date...

### Time of Measurement

### Comments/Observations

Write something...

## Feedback and Iteration

Gathering feedback on implemented changes and making necessary adjustments to optimize ongoing performance.

### Summary of User Feedback Received

Write something...

### Number of Users Providing Feedback

Enter a number...

### Overall Sentiment of Feedback (Positive, Negative, Neutral)

- ☐ Positive
- ☐ Negative
- ☐ Neutral

### Specific Suggestions for Improvement

Write something...

### Areas of Process Needing Further Refinement (Select all that apply)

- ☐ Efficiency
- ☐ Clarity
- ☐ User Experience
- ☐ Compliance
- ☐ Communication

### Date of Feedback Review

Enter date...

## Documentation and Reporting

Maintaining comprehensive records of continuous improvement activities and reporting findings to stakeholders.

### Report Creation Date

Enter date...

### Summary of Improvements Implemented

Write something...

### Number of Process Steps Modified

Enter a number...

### Estimated Cost Savings (USD)

Enter a number...

### Supporting Data/Graphs

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### Report Distribution Method

- ☐ Email
- ☐ Shared Drive
- ☐ Printed Copy

### Approver Signature

### Comments/Notes/Next Steps

Write something...

## Risk Assessment & Mitigation

Identifying and mitigating potential risks associated with implemented changes.

### Describe Potential Risks Associated with the Improvement

Write something...

### Assign Risk Severity Score (1-10)

Enter a number...

### Assign Risk Probability Score (1-10)

Enter a number...

### Risk Category (e.g., Quality, Safety, Compliance)

- ☐ Quality
- ☐ Safety
- ☐ Compliance
- ☐ Financial
- ☐ Reputational

**Proposed Mitigation Strategies**

Write something...

**Residual Risk Severity Score (After Mitigation)**

Enter a number...

**Date Mitigation Plan Implemented**

Enter date...

**Mitigation Plan Review & Approval**