



# Pharmaceutical Deviation Trend Analysis Checklist

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## Deviation Identification & Data Collection

Gather and record details of each deviation event, including date, time, product, equipment, personnel involved, and initial assessment.

### Deviation Date

Enter date...

### Deviation Time

Enter time...



### Product Affected

- Product A
- Product B
- Product C
- Other

### Equipment Involved

- Equipment 1
- Equipment 2
- Equipment 3
- None

### Brief Description of Deviation

Write something...

### Batch Number (if applicable)

Enter a number...

### Personnel Involved (Primary)

- Operator 1
- Operator 2
- Technician 1
- Other

## Categoryzation & Coding

Assign appropriate categories and codes to each deviation based on pre-defined classifications (e.g., equipment failure, operator error, raw material issue).

### Deviation Category

- Equipment Failure
- Raw Material Issue
- Process Deviation
- Personnel Error
- Facility Issue
- Documentation Error

### Severity Level

- Minor
- Major
- Critical

### Deviation Number/ID

Enter a number...

### Affected Systems/Areas

- Manufacturing
- Quality Control
- Packaging
- Warehouse

### Coding System

- Company Internal Code
- Standard Industry Classification

# Root Cause Analysis Documentation

Detail the steps taken to investigate the root cause of each deviation, including CAPA plan assignment.

## Detailed Description of the Deviation Event

Write something...

## Initial Hypothesis of Root Cause

Write something...

## Investigation Techniques Employed (e.g., 5-Why, Fishbone Diagram)

- 5-Why Analysis
- Fishbone Diagram
- Fault Tree Analysis
- Process Mapping
- Other (Specify)

### Summary of Investigation Findings

Write something...

### Identified Root Cause(s)

Write something...

### Number of Contributing Factors

Enter a number...

### Investigator Signature

### Date of Root Cause Determination

Enter date...

## Trend Identification & Analysis

Analyze collected data to identify patterns, frequencies, and potential systemic issues across deviations.

### Number of Deviations in Trend

Enter a number...

### Identified Trend Type (e.g., Increasing, Decreasing, Stable)

- Increasing
- Decreasing
- Stable
- Unpredictable

### Detailed Description of Observed Trend

Write something...

### Start Date of Trend Observation

Enter date...

### End Date of Trend Observation (if applicable)

Enter date...

### Affected Process Steps (Select all that apply)

- Raw Material Receipt
- Manufacturing
- Packaging
- Storage
- Distribution

# Pareto Chart Creation

Develop a Pareto chart to visually represent the relative importance of different deviation categories.

## Deviation Frequency

## Deviation Impact Score (e.g., Cost, Time, Quality)

## Deviation Category (for Pareto Chart Sorting)

- Equipment Failure
- Operator Error
- Raw Material Issue
- Process Deviation
- Environmental Concern
- Other

## Notes on Pareto Chart Data

## Pareto Chart Visual Representation (Image/Graph)

 Upload File

# Corrective & Preventative Actions (CAPA) Tracking

Document and track the implementation and effectiveness of CAPA plans to address identified trends and prevent recurrence.

## CAPA Plan Description

Write something...

## CAPA Plan Implementation Date

Enter date...

## Estimated Completion Time (Days)

Enter a number...

## Assigned Departments/Teams

- Quality Assurance
- Manufacturing
- Engineering
- Validation
- Regulatory Affairs

**Planned Completion Date**

Enter date...

**CAPA Owner Signature**

**Status (%)**

Enter a number...

## Effectiveness Verification

Verify and document the effectiveness of implemented CAPA plans, demonstrating a reduction in the frequency or impact of identified deviation trends.

**Post-CAPA Deviation Frequency (Events/Month)**

Enter a number...

**Deviation Frequency Reduction (%)**

Enter a number...

### Date of Initial Effectiveness Review

Enter date...

### Detailed Description of Verification Activities Performed

Write something...

### Overall Effectiveness Assessment

- Effective
- Partially Effective
- Ineffective

### Justification for Effectiveness Assessment (if not 'Effective')

Write something...

### Reviewer Signature

Enter date...

### Next Review Date

Enter date...

## Reporting & Review

Generate reports summarizing deviation trends and their analysis, and review findings with relevant stakeholders (e.g., Quality Assurance, Manufacturing).

### Report Generation Date

Enter date...

### Total Deviations Analyzed in Reporting Period

Enter a number...

### Overall Trend Assessment (Based on Analysis)

- Improving
- Stable
- Worsening

### Summary of Key Trend Observations

Write something...

### Supporting Trend Charts/Graphs

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### **Recommendations for Future Investigation/Improvement**

Write something...

### **Reviewer Signature**

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