



# Pharmaceutical Deviation Trend Analysis Checklist

## Deviation Identification & Data Collection

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

### Deviation Date

### Deviation 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

## Categorization & 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

Enter a number...

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

Enter a number...

### Deviation Category (for Pareto Chart Sorting)

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

### Notes on Pareto Chart Data

Write something...

### 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

### 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**