ChecklistGuro

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

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

Upload File

Recommendations for Future Investigation/Improvement

Write something...

Reviewer Signature