ChecklistGuro

Pharmaceutical Deviation Management Checklist

Deviation Identification & Reporting

Initial assessment and formal reporting of the deviation.

Date of Deviation Occurrence

Enter date...

Time of Deviation Occurrence

Detailed Description of Deviation

Write something...

Deviation Category

- [ ] Manufacturing
- [ ] Equipment
- [ ] Raw Material
- [ ] Process
- [ ] Packaging
- [ ] Other

Severity Level

- [ ] Minor
- [ ] Moderate
- [ ] Major

Batch Number (if applicable)

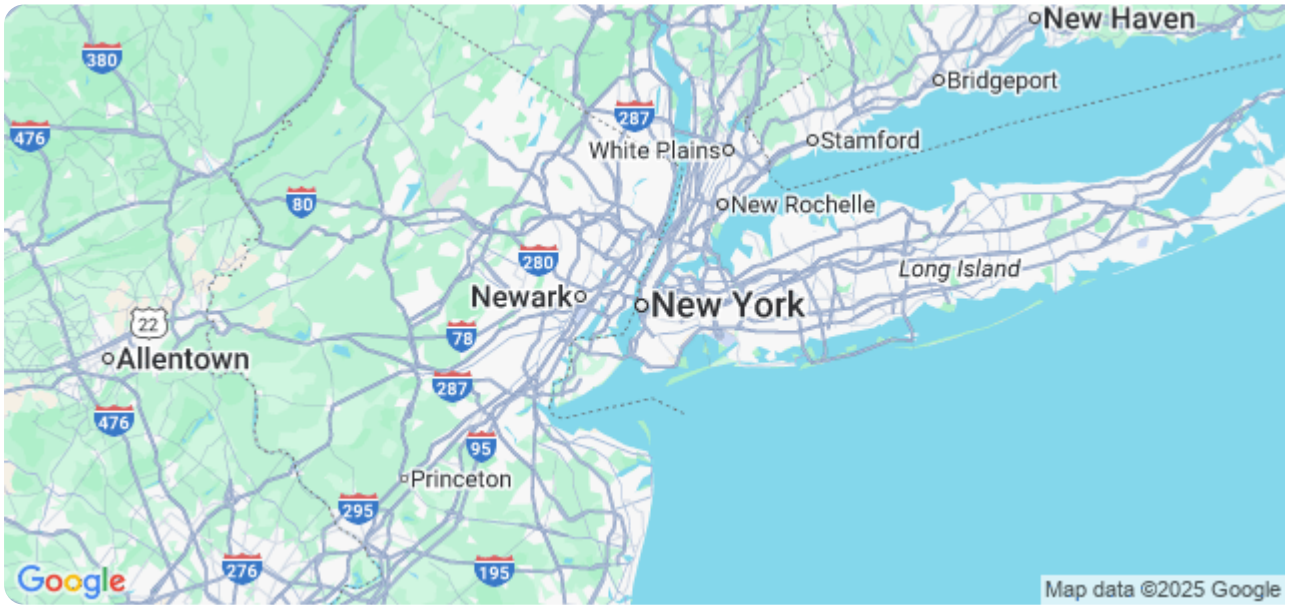
Enter a number...

Reported By (Name)

Write something...

Location of Deviation

Set My Current Location



Deviation Investigation

Root cause analysis and determination of contributing factors.

Detailed Description of Deviation

Write something...

Possible Root Causes Identified

Write something...

Potential Contributing Factors

- [ ] Equipment Failure
- [ ] Human Error
- [ ] Process Out of Control
- [ ] Raw Material Issue
- [ ] Documentation Error
- [ ] Training Deficiency

Number of Times Observed (if recurring)

Enter a number...

Date of Initial Observation

Enter date...

Supporting Documentation (e.g., logs, reports)

Upload File

Investigation Team Lead

Corrective and Preventive Actions (CAPA)

Development and implementation of actions to prevent recurrence.

Detailed Description of Corrective Action

Write something...

Detailed Description of Preventive Action

Write something...

Estimated Cost of Corrective Action (USD)

Enter a number...

Planned Implementation Date of Corrective Action

Enter date...

Planned Implementation Date of Preventive Action

Enter date...

Responsible Department for CAPA Implementation

- [ ] Quality Assurance
- [ ] Manufacturing
- [ ] Engineering
- [ ] Validation
- [ ] Other

CAPA Priority

- [ ] High
- [ ] Medium
- [ ] Low

Signature of Person Implementing CAPA

CAPA Effectiveness Verification

Assessment of whether CAPAs have resolved the deviation and prevented recurrence.

Verification Start Date

Enter date...

Verification Completion Date

Enter date...

Verification Outcome

- [ ] Effective
- [ ] Partially Effective
- [ ] Ineffective

Detailed Description of Verification Activities

Write something...

Number of Instances of Deviation Since CAPA Implementation

Enter a number...

Summary of Data Analyzed for Verification

Write something...

Were there any unexpected findings during verification?

- [ ] Yes
- [ ] No

If yes, describe unexpected findings

Write something...

Documentation & Record Keeping

Ensuring complete and accurate documentation throughout the deviation management process.

Deviation Description (Detailed)

Write something...

Supporting Documentation (e.g., Batch Records, Lab Reports)

Upload File

Date of Record Creation

Enter date...

Time of Record Creation

Document Control Number

Enter a number...

Signature of Person Completing Record

Record Status (Draft/Reviewed/Approved/Closed)

- [ ] Draft
- [ ] Reviewed
- [ ] Approved
- [ ] Closed

Risk Assessment & Impact Analysis

Evaluating the potential impact of the deviation on product quality, patient safety, and regulatory compliance.

Estimated Potential Impact Score (1-5)

Enter a number...

Potential Impact Areas Affected

- [ ] Product Quality
- [ ] Patient Safety
- [ ] Regulatory Compliance
- [ ] Manufacturing Process
- [ ] Data Integrity

Description of Potential Risk

Write something...

Probability of Recurrence (1-5)

Enter a number...

Severity Assessment

- [ ] Minor
- [ ] Moderate
- [ ] Major

Justification for Risk Assessment

Write something...

Closure & Review

Formal closure of the deviation and review of the entire process for improvement.

Deviation Closure Date

Enter date...

Summary of Review Findings

Write something...

Overall Risk Reassessment (Post-CAPA)

- [ ] High
- [ ] Medium
- [ ] Low

Recommendations for Process Improvement

Write something...

Reviewer Signature

Reviewer Name

Write something...

Revision Number

Enter a number...