ChecklistGuro

Pharmaceutical CAPA Management Checklist

Deviation Identification & Reporting

Ensuring proper identification, documentation, and initial assessment of deviations.

Deviation Date

Enter date...

Deviation Time

Deviation Description

Write something...

Deviation Severity

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

Deviation Category

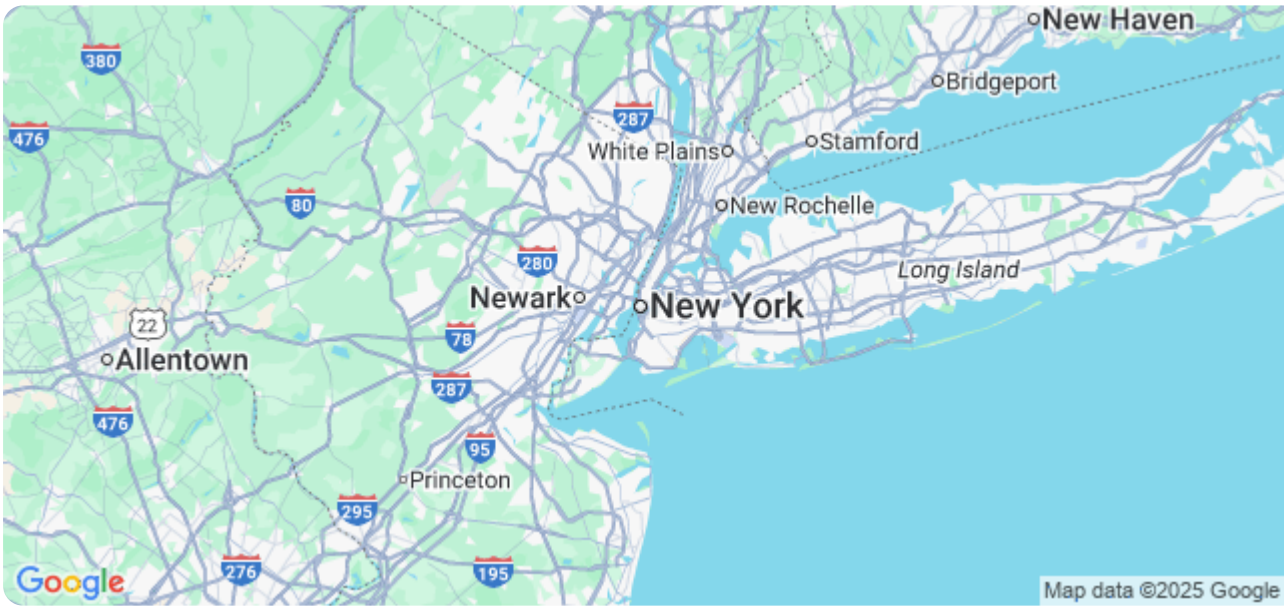
- [ ] Manufacturing
- [ ] Quality Control
- [ ] Equipment
- [ ] Personnel
- [ ] Other

Batch/Lot Number (if applicable)

Enter a number...

Location of Deviation

Set My Current Location



Supporting Documentation (e.g., photos, records)

Upload File

Root Cause Investigation

Comprehensive analysis to determine the underlying cause(s) of the deviation.

Detailed Description of Deviation

Write something...

Potential Root Causes (Select All That Apply)

- [ ] Equipment Failure
- [ ] Human Error
- [ ] Process Variation
- [ ] Raw Material Issue
- [ ] Documentation Error
- [ ] Training Deficiencies
- [ ] Other (Specify)

Specify 'Other' Root Cause (if selected)

Write something...

Number of Times Similar Issue Occurred Previously (if applicable)

Enter a number...

Date of Initial Observation/Event

Enter date...

Supporting Data/Analysis (e.g., statistical analysis, trend charts)

Write something...

Attach Supporting Documents (e.g., lab reports, equipment logs)

Upload File

Corrective Action Development

Defining and documenting the actions required to prevent recurrence.

Detailed Description of Corrective Action(s)

Write something...

Estimated Cost of Corrective Action (USD)

Enter a number...

Action Responsibility (Primary Owner)

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

Target Completion Date

Enter date...

Affected Departments/Functions

- [ ] Manufacturing
- [ ] Quality Control
- [ ] Engineering
- [ ] Supply Chain
- [ ] Regulatory Affairs

Action Owner Signature

Preventive Action Implementation

Establishing proactive measures to address potential issues.

Detailed Description of Preventive Action

Write something...

Estimated Cost of Implementation

Enter a number...

Planned Implementation Start Date

Enter date...

Planned Implementation Completion Date

Enter date...

Departments Responsible

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

Supporting Documentation (e.g., SOP Updates, Engineering Drawings)

Upload File

Risk Mitigation Strategy

Write something...

CAPA Effectiveness Verification

Evaluating the impact of corrective and preventive actions.

Verification Start Date

Enter date...

Verification End Date

Enter date...

Number of Deviations Reopened (Post CAPA)

Enter a number...

Number of New Deviations Related to Root Cause (Post CAPA)

Enter a number...

Overall Effectiveness Rating (Based on Data)

- [ ] Highly Effective
- [ ] Moderately Effective
- [ ] Slightly Effective
- [ ] Not Effective

Summary of Data Analyzed & Findings

Write something...

Was the original Root Cause Effectively Addressed?

- [ ] Yes
- [ ] No
- [ ] Partially

Additional Comments or Observations

Write something...

CAPA Documentation & Record Keeping

Maintaining complete and accurate records of the CAPA process.

CAPA Origination Date

Enter date...

Detailed Description of Deviation & Initial Assessment

Write something...

CAPA Number/ID

Enter a number...

Summary of Root Cause Investigation Findings

Write something...

Supporting Documentation (e.g., lab reports, investigation files)

Upload File

Detailed Description of Corrective & Preventive Actions

Write something...

Corrective Action Completion Date

Enter date...

CAPA Owner Signature

CAPA Training & Communication

Ensuring staff are trained on CAPA procedures and effectively communicating updates.

Number of Employees Trained

Enter a number...

Training Completion Date

Enter date...

Training Format (e.g., Online, Classroom)

- [ ] Online
- [ ] Classroom
- [ ] Hybrid

Brief Summary of Training Content

Write something...

Topics Covered in Training (Select all that apply)

- [ ] Deviation Management
- [ ] Root Cause Analysis
- [ ] Corrective Actions
- [ ] Risk Assessment
- [ ] Documentation Requirements

Trainer Signature

Training Material Version

Write something...

CAPA Closure & Review

Formal closure of CAPA items and periodic review of the CAPA system's effectiveness.

Date of CAPA Closure

Enter date...

Summary of CAPA Resolution and Effectiveness

Write something...

Number of Recurrences Post-Closure (if any)

Enter a number...

CAPA Closure Status

- [ ] Closed
- [ ] Pending Further Action
- [ ] Reopened

Signature of Reviewer

Reviewer Name

Write something...

Reviewer Title

Write something...