ChecklistGuro

Pharmaceutical Cleaning Deviation Investigation Checklist

Deviation Identification & Initial Assessment

Details surrounding the initial discovery and preliminary evaluation of the cleaning deviation.

Date of Deviation Discovery

Enter date...

Time of Deviation Discovery

Brief Description of Deviation

Write something...

Initial Severity Assessment (e.g., Minor, Moderate, Major)

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

Reporting Source (e.g., Operator, QA, Maintenance)

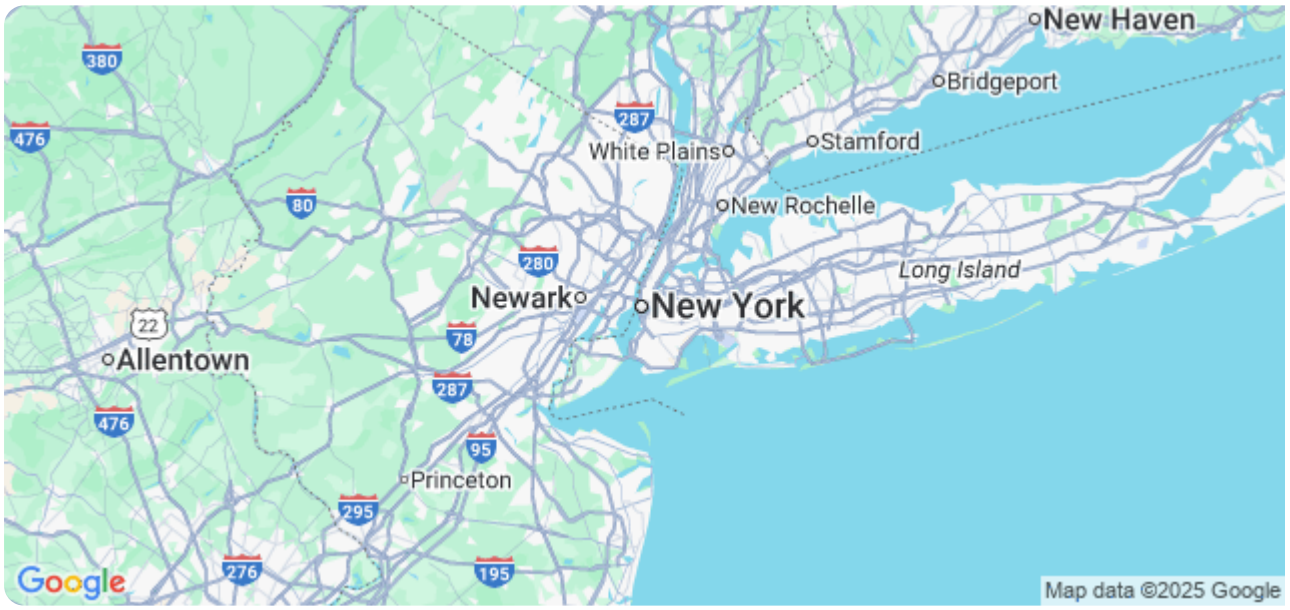
- [ ] Operator
- [ ] QA
- [ ] Maintenance
- [ ] Other

Deviation Number/ID (if assigned)

Write something...

Equipment Location (Area/Room)

Set My Current Location



Initial Assessment Sign-off

Deviation Details & Scope

Comprehensive information about the specific cleaning issue, affected equipment, and potentially impacted batches.

Deviation Reference Number

Write something...

Date of Deviation Occurrence

Enter date...

Time of Deviation Occurrence

Equipment ID/Name

Write something...

Detailed Description of Deviation

Write something...

Affected Product(s)/Batch(es)

- [ ] Product/Batch 1
- [ ] Product/Batch 2
- [ ] Product/Batch 2

Quantity Affected (if applicable)

Enter a number...

Initial Assessment of Impact

Write something...

Root Cause Analysis

Investigation and documentation of the underlying reasons for the cleaning deviation.

Describe the observed cleaning failure (e.g., visual residue, analytical data).

Write something...

Potential Contributing Factors (Select all that apply)

- [ ] Inadequate Cleaning Procedure
- [ ] Incorrect Cleaning Agent
- [ ] Equipment Malfunction
- [ ] Operator Error
- [ ] Insufficient Rinse
- [ ] Incorrect Water Quality

Detailed explanation of the investigation performed to identify the root cause.

Write something...

Temperature during cleaning (if applicable)

Enter a number...

Date of Cleaning Event

Enter date...

Root Cause Category (Select one)

- [ ] Procedure
- [ ] Equipment
- [ ] Material
- [ ] Training

Specific evidence supporting the identified root cause (e.g., analytical reports, observation logs).

Write something...

Corrective Action Plan (CAP)

Steps taken to correct the immediate deviation and prevent recurrence.

Detailed Description of Immediate Corrective Action Taken

Write something...

Date Corrective Action Initiated

Enter date...

Time Corrective Action Initiated

Quantity of Cleaning Agent/Solution Used (if applicable)

Enter a number...

Method of Cleaning (e.g., Manual, Automated)

- [ ] Manual
- [ ] Automated

Signature of Person Performing Corrective Action

Supporting Documentation (e.g., Photos, Cleaning Logs)

Upload File

Preventative Action Plan (PAP)

Proactive measures to eliminate the root cause and improve cleaning procedures.

Detailed Description of Preventative Action

Write something...

Affected Cleaning Procedures to Revise

- [ ] SOP - Equipment Cleaning
- [ ] Cleaning Log Templates
- [ ] Training Materials
- [ ] Cleaning Validation Protocol

Frequency of Revised SOP Review (e.g., Quarterly)

Enter a number...

Target Completion Date for Preventative Actions

Enter date...

Responsible Personnel Signature (PAP)

Training Required for Personnel?

- [ ] Yes
- [ ] No

Supporting Documentation (e.g., revised SOP)

Upload File

Verification & Validation

Confirmation that the corrective and preventative actions are effective and the equipment/process meets cleaning requirements.

Verification/Validation Start Date

Enter date...

Verification/Validation Start Time

Cleaning Cycle Time Verified (minutes)

Enter a number...

Cleaning Temperature Verified (°C)

Enter a number...

Concentration of Cleaning Agent Verified (%)

Enter a number...

Cleaning Validation Method Used

- [ ] Visual Inspection
- [ ] ATP Monitoring
- [ ] Residue Testing

Supporting Documentation (e.g., ATP reports, residue test results)

Upload File

Validation Analyst Signature

Documentation Review & Approval

Verification of complete and accurate record-keeping, including signatures and dates for all steps.

Document Review Date

Enter date...

Summary of Document Review Findings

Write something...

Document Accuracy Assessment

- [ ] Accurate
- [ ] Minor Discrepancies
- [ ] Significant Discrepancies

Reviewer Signature

Reviewer Name (Printed)

Write something...

Document Version Number

Enter a number...

Approval Status

- [ ] Approved
- [ ] Rejected
- [ ] Pending Revision

Batch Impact Assessment

Evaluation of potential impact on product quality and patient safety, including potential recalls or retesting.

Summary of Potential Product Impact

Write something...

Number of Potentially Affected Batches

Enter a number...

Batch Status Review Required?

- [ ] Yes
- [ ] No

Affected Product Attributes (e.g., sterility, assay, impurities)

- [ ] Sterility
- [ ] Assay
- [ ] Impurities
- [ ] Appearance
- [ ] Other

Date of Next Stability Testing (if applicable)

Enter date...

Recall Action Required?

- [ ] Yes
- [ ] No

Justification for Recall Decision (if applicable)

Write something...

Closure and Sign-Off

Formal closure of the investigation with responsible personnel sign-off indicating completion and approval.

Closure Date

Enter date...

Investigator Signature

Quality Assurance Reviewer Signature

Deviation ID/Reference Number

Enter a number...

Summary of Findings & Conclusions

Write something...

Deviation Status (Closed, Pending, Reopened)

- [ ] Closed
- [ ] Pending
- [ ] Reopened