ChecklistGuro

# Pharmaceutical Overage Evaluation Checklist

## Initial Data Gathering

Collecting all necessary data related to the overage, including batch records, analytical results, and inventory records.

**Batch Number**

Enter a number...

**Date of Overage Detection**

Enter date...

**Time of Overage Detection**

**Overage Type (e.g., API, Excipient, Impurity)**

- [ ] API
- [ ] Excipient
- [ ] Impurity
- [ ] Other

**Original Quantity (Units)**

Enter a number...

**Overage Quantity (Units)**

Enter a number...

**Initial Observation/Description of Overage**

Write something...

# Analytical Review

Detailed assessment of analytical data to confirm overage and identify potential causes.

**Measured Overage Amount**

Enter a number...

**Specification Limit**

Enter a number...

**Acceptance Criteria (e.g., % allowable)**

Enter a number...

**Analytical Method Used**

- [ ] HPLC
- [ ] GC
- [ ] UV-Vis
- [ ] Titration
- [ ] Other

**Analytical Data Comments/Observations**

Write something...

**Date of Analysis**

Enter date...

**Attachment of Chromatogram/Analytical Report**

Upload File

# Process & Material Investigation

Investigation of manufacturing processes and raw material sources to determine contributing factors to the overage.

**Describe the Manufacturing Process Step Involved**

Write something...

**Material Source Verification Status**

- [ ] Verified
- [ ] Pending
- [ ] Not Applicable

**Batch Size at Time of Overage**

Enter a number...

**Date of Material Receipt**

Enter date...

**Describe any deviations from standard operating procedures (SOPs)**

Write something...

**Upload relevant batch records or reports**

Upload File

**Potential Material Contributing Factors**

- [ ] Raw Material Specification
- [ ] Supplier Change
- [ ] Storage Conditions
- [ ] Handling Procedures

# Impact Assessment

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

**Estimated Overage Quantity (Units)**

Enter a number...

**Potential Impact on Product Quality?**

- [ ] No Impact
- [ ] Minor Impact
- [ ] Moderate Impact
- [ ] Significant Impact

**Potential Patient Safety Concerns?**

- [ ] None
- [ ] Low
- [ ] Moderate
- [ ] High

**Detailed Explanation of Potential Quality Impacts**

Write something...

**Potential Regulatory Reporting Requirements?**

Write something...

**Date of Regulatory Notification (if applicable)**

Enter date...

**Estimated Cost of Overage (Material, Labor, Waste)**

Enter a number...

# Root Cause Determination

Identifying the fundamental reason(s) for the overage occurrence.

**Detailed Description of the Suspected Root Cause(s)**

Write something...

**Potential Contributing Factors (Select all that apply)**

- [ ] Equipment Malfunction
- [ ] Process Deviation
- [ ] Human Error
- [ ] Material Variation
- [ ] Analytical Method Issue
- [ ] Documentation Error

**Estimated Frequency of Similar Past Occurrences (if known)**

Enter a number...

**Date of Initial Suspicion/Observation of Root Cause**

Enter date...

**Confidence Level in Root Cause Identification (High, Medium, Low)**

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

**Supporting Evidence & Data Analysis Related to Root Cause**

Write something...

## Corrective and Preventative Actions (CAPA)

Developing and implementing corrective and preventative actions to prevent recurrence. Includes assignment of responsibility and timelines.

**Detailed Description of Corrective Action**

Write something...

**Detailed Description of Preventative Action**

Write something...

**Estimated Cost of Implementation (USD)**

Enter a number...

**Planned Implementation Date**

Enter date...

**Responsible Department**

- [ ] Manufacturing
- [ ] Quality Assurance
- [ ] Engineering
- [ ] Supply Chain

**Risk Level After Implementation**

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

**Quality Assurance Reviewer Signature**

## Documentation Review & Approval

Ensuring all findings, assessments, and corrective actions are thoroughly documented and approved by relevant stakeholders.

**Summary of Findings and Assessment**

Write something...

**Quality Assurance Reviewer Signature**

**Date of QA Review**

Enter date...

**Review Status**

- [ ] Approved
- [ ] Rejected
- [ ] Requires Revision

**Comments/Reason for Rejection (if applicable)**

Write something...

**Reviewer Approval Signature (if Approved)**

**Date of Approval**

Enter date...

# Verification & Follow-up

Verifying the effectiveness of implemented CAPAs and establishing ongoing monitoring to prevent future occurrences.

**CAPA Implementation Date**

Enter date...

**Number of Batches Reviewed Post-Implementation**

Enter a number...

**Effectiveness of CAPA – Initial Assessment**

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

**Justification for CAPA Effectiveness Assessment (if not 'Effective')**

Write something...

**Next Scheduled Review Date**

Enter date...

**Reviewer Signature**

## Summary of Follow-Up Observations & Findings

Write something...