



# Pharmaceutical Quality Risk Management Checklist

## Risk Identification

Activities related to identifying potential hazards and risks within pharmaceutical processes.

### Brief Description of Process/Activity

Write something...

### Potential Hazard/Risk Description

Write something...

### Process Steps Involved (Select All That Apply)

- ☐ Raw Material Sourcing
- ☐ Manufacturing
- ☐ Packaging
- ☐ Storage
- ☐ Distribution
- ☐ Cleaning/Sanitation

### Regulatory/Guidance Relevance

- ☐ GMP Regulations
- ☐ ICH Guidelines
- ☐ Company SOPs
- ☐ Other (Specify)

### Date of Initial Risk Identification

Enter date...

### Identification Source (e.g., Audit Findings, Deviation Reports)

Write something...

## Risk Analysis - Severity Assessment

Evaluating the potential severity of impact if a risk were to occur.

### Potential Impact on Patient Safety

- ☐ Negligible
- ☐ Minor
- ☐ Moderate
- ☐ Major
- ☐ Critical

### Potential Impact on Product Quality

- ☐ None
- ☐ Minor Deviation
- ☐ Significant Deviation
- ☐ Batch Rejection
- ☐ Product Recall

### Estimated Number of Patients Potentially Affected

Enter a number...

### Description of Potential Adverse Effects

Write something...

### Impact on Regulatory Compliance

- ☐ No Impact
- ☐ Minor Deviation
- ☐ Significant Deviation
- ☐ Potential Warning Letter

### Estimated Financial Loss (if applicable)

Enter a number...

## Risk Analysis - Probability Assessment

Estimating the likelihood of a risk event occurring.

### Probability Scale Value (1-5)

Enter a number...

### Justification for Probability Rating

Write something...

### Frequency of Occurrence

- ☐ Once per year or less
- ☐ Several years
- ☐ Several months
- ☐ Several weeks
- ☐ Several days
- ☐ Daily

### Factors Influencing Probability

Write something...

### Estimated Frequency (Events/Year)

Enter a number...

## Risk Evaluation - Prioritization

Ranking risks based on their combined severity and probability.

### Severity Score

Enter a number...

### Probability Score

Enter a number...

### Risk Score (Severity x Probability)

Enter a number...

### Risk Priority Category

- ☐ High
- ☐ Medium
- ☐ Low

### Justification for Prioritization

Write something...

### Risk Ownership Assigned

- ☐ Quality Assurance
- ☐ Manufacturing
- ☐ Engineering
- ☐ Other

## Risk Control Measures - Existing

Documentation of existing controls currently in place to mitigate identified risks.

**Detailed Description of Existing Control**

Write something...

**Control Type (e.g., Preventative, Detective, Corrective)**

- ☐ Preventative
- ☐ Detective
- ☐ Corrective

**Frequency of Control Execution (e.g., daily, weekly, monthly)**

Enter a number...

**Last Review/Verification Date of Control**

Enter date...

**Applicable Regulations/Guidelines Controlled By**

- ☐ cGMP
- ☐ ICH Guidelines
- ☐ FDA Regulations
- ☐ Company SOPs

**Reviewer Signature**

# Risk Control Measures - Proposed

Planning and documenting proposed new or enhanced controls to address prioritized risks.

## Detailed Description of Proposed Control

Write something...

## Estimated Cost of Implementation

Enter a number...

## Target Implementation Date

Enter date...

## Responsible Department/Team

- ☐ Manufacturing
- ☐ Quality Assurance
- ☐ Engineering
- ☐ Supply Chain

## Control Type(s) (e.g., Administrative, Engineering, Procedural)

- ☐ Administrative
- ☐ Engineering
- ☐ Procedural
- ☐ Equipment Modification

### Supporting Documentation (e.g., SOP, Drawings)

 Upload File

### Justification for Proposed Control

Write something...

## Risk Control Implementation

Tracking the implementation of proposed risk control measures and confirming their effectiveness.

### Implementation Start Date

Enter date...

### Planned Completion Date

Enter date...

### Estimated Cost of Implementation

Enter a number...

### Description of Implementation Activities Performed

Write something...



### Implementation Status

- ☐ Not Started
- ☐ In Progress
- ☐ Completed
- ☐ Delayed

### Implemented By

### Supporting Documentation (e.g., training records, SOP revisions)

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### Actual Cost of Implementation

Enter a number...

## Risk Review & Monitoring

Establishing procedures for regularly reviewing and monitoring the effectiveness of risk management processes and controls.

### Last Review Date

Enter date...

### Frequency of Review (in months)

Enter a number...

### Review Outcome (Satisfactory/Needs Improvement/Unsatisfactory)

- ☐ Satisfactory
- ☐ Needs Improvement
- ☐ Unsatisfactory

### Summary of Review Findings

Write something...

### Corrective Actions Identified (if any)

Write something...

### Target Completion Date for Corrective Actions

Enter date...

### Reviewer Signature

### Risk Status after Review (Increased/Decreased/No Change)

- ☐ Increased
- ☐ Decreased
- ☐ No Change

## Documentation & Record Keeping

Ensuring complete and accurate records of the entire risk management process, including identification, analysis, evaluation, and controls.

**Risk Assessment Review Date**

Enter date...

**Summary of Risk Assessment Findings**

Write something...

**Supporting Documentation (e.g., protocols, reports)**

 Upload File

**Record Status (Active, Archived, Superseded)**

- ☐ Active
- ☐ Archived
- ☐ Superseded

**Document Version Number**

Enter a number...

**Reviewer Signature**

**Comments/Notes Regarding Documentation**

Write something...