ChecklistGuro

Pharmaceutical Quality Risk Management Checklist

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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)

Upload File

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...