Leucine

Quality Risk Management

Audit Readiness Checklist

I. Quality System

	Yes	No	NA
Is a comprehensive risk assessment conducted before implementing any specification changes?			
Are risk assessments regularly reviewed and updated based on validation and production data?			
Are documented procedures established for conducting comprehensive risk assessments?			
Does the Quality Unit routinely evaluate the wider impact of identified issues?			
Has the Quality Unit undergone training on quality risk management?			
Is there an active monitoring and review system for quality risk management?			
Are the roles and authorities of the Quality Unit clearly defined?			
Are routine audits conducted to ensure compliance with defined responsibilities?			
Is there a robust governance framework to review and update roles regularly?			
Is there a documented procedure for initiating Notice of Quality Events (NQEs)?			

II. Production System

	Yes	No	NA
Are risk assessments conducted for equipment found to have deficiencies?			
Has a risk assessment been conducted for all production processes?			
Are risks monitored and controlled on an ongoing basis?			
Is there a CAPA process in place for risk management?			
Are validation and revalidation activities executed and documented appropriately?			
Are errors in production fully investigated and documented?			
Are QRM principles integrated into routine production operations?			
Is statistical trend analysis applied to deviations in production?			
Are recurring deviations identified through risk-based monitoring?			
Is a risk management plan established for aseptic filling operations?			

III. Facilities & Equipment System

	Yes	No	NA
Are HEPA filters in ISO 5 areas properly validated and documented?			
Are aseptic connection processes clearly defined and followed?			
Has a risk assessment been conducted for unvalidated or revalidated systems?			
Is there a process to reassess risks when validation deviations are identified?			
Are preventive maintenance and calibration activities risk-based and tracked?			
Are equipment cleaning and documentation oversight governed by risk protocols?			
Is there a system for identifying and mitigating risks in cleaning processes?			
Has a risk assessment been conducted post-maintenance shutdown?			
Has a risk assessment been performed for equipment breakdowns?			
Is a facility risk management plan periodically reviewed and approved by QA?			

IV. Materials System

	Yes	No	NA
Does the Quality Control Unit have authority to approve/reject materials?			
Are all raw materials approved by the Quality Control Unit before use?			
Are comprehensive risk assessments conducted for all raw materials?			
Are supplier management and product release risks periodically assessed?			
Are protocols in place to assess supplier grade changes?			
Was a risk assessment performed for pharmaceutical vs. non-pharmaceutical grade changes?			
Are incoming material defects handled with documented risk-based procedures?			
Is there a risk management plan for animal-derived materials and drugs?			
Is QA involved in decision-making for material release and rejections?			
Is supplier performance monitored and re-evaluated based on risk?			

V. Laboratory Control System

	Yes	No	NA
Are laboratory OOS results investigated with risk-based procedures?			
Are OOT results documented and reviewed under QRM?			
Are stability studies performed with risk assessment considerations?			
Has a risk assessment been performed for method transfers?			
Are established risk mitigation strategies applied to method transfers?			
Are laboratory computerized systems validated to manage risks?			
Is trend analysis performed for OOS/OOT results?			
Is there a lab risk management plan reviewed annually?			
Is data integrity risk monitored in laboratory operations?			
Are microbiological and sterility testing risks assessed and mitigated?			

VI. Packaging & Labeling System

	Yes	No	NA
Are risk assessments performed for visual and AQL inspection failures?			
Are training and awareness programs in place for risk in visual inspections?			
Is there a visual defect library accessible to inspectors?			
Are risk management procedures in place for labeling errors?			
Are packaging recalls addressed with a defined QRM procedure?			
Are risk assessments conducted for rework or repackaging operations?			
Are quality complaints regarding packaging evaluated for health hazards?			
Are risk-based rejection criteria applied in labeling inspections?			
Are packaging-related CAPAs integrated into risk management reviews?			
Are audit trails for laboratory records maintained?			

VII. Documentation & Change Control

	Yes	No	NA
Are risk assessments documented for each deviation?			
Is there a standard procedure for performing risk assessments?			
Are risk assessments reviewed and updated regularly?			
Are outcomes of risk assessments communicated to staff?			
Is document control included in the QRM framework?			
Are risk mitigation strategies documented for document control?			
Is ongoing monitoring performed for document access and issuance risks?			
Is a risk assessment conducted for missed design reviews?			
Are risk management principles integrated into design reviews?			
Are risk assessments updated to address risks from inadequate design and control?			

VIII. Training & Personnel

	Yes	No	NA
Are staff adequately trained to conduct risk assessments?			
Is continuous training provided to QA/QC staff on QRM?			
Are regular training sessions conducted for defect classification?			
Are training records for QRM complete and updated?			
Are employees trained to identify contamination risks?			
Are refresher programs held for high-risk QRM processes?			
Are staff trained on segregation of roles between QA and validation?			
Is training conducted on contamination risks from supporting equipment?			
Are training programs in place for deviation handling and risk assessment?			
Are inspectors trained to recognize risk trends during inspections?			

IX. Complaint & Recall Management

	Yes	No	NA
Are risks associated with complaint management assessed periodically?			
Are complaint trends prioritized by severity using risk-based evaluation?			
Is there a documented process for handling complaints exceeding timelines?			
Are risk assessments performed for supplier recall notifications?			
Are preventive actions from complaint trends integrated into QRM?			
Is there a risk management plan for handling product recalls?			
Are complaints involving adverse events escalated with risk criteria?			
Are vigilance reports trended and reviewed under QRM?			
Is complaint-related CAPA effectiveness assessed through risk reviews?			
Are labeling/packaging-related complaints included in QRM reviews?			

X. Monitoring & Continuous Improvement

	Yes	No	NA
Are risk management reviews integrated into management reviews?			
Are quality signals incorporated into continuous risk assessment processes?			
Is there a periodic review of the overall QRM plan?			
Are high-risk queries identified and prioritized in monitoring systems?			
Are findings from risk assessments integrated into CAPA planning?			
Is risk management documentation continuously updated with new findings?			
Are periodic audits conducted to assess QRM effectiveness?			
Are QRM procedures aligned with current regulatory standards?			
Is continuous improvement incorporated into QRM strategies?			
Are QRM processes benchmarked against industry best practices?			

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AI Powered Batch Execution

Batch Intelligence
Deliver On-Time In Full

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Integrate Production logbooks

Quality

AI Investigator
Close Investigations Faster

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DMS
Schedule A Demo

Contamination Control

Environmental Monitoring
Plan Track & Analyse EM Samples

Cleaning Validation
FDA Ready cleaning validation

Compliant With

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International Organization for Standardization ISO 27001
AICPA SOC 2 Formerly SAS 70 Reports
FDA 21 CFR Part 11
EU GMP

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