Leucine

CAPA Management

Audit Readiness Checklist

I. Documentation & Record Control

	Yes	No	NA
CAPA Recordkeeping & Accessibility			
• Has the CAPA procedure been updated to include specific actions for addressing test method variability and negative trend identifications?	☐	☐	☐
• Are CAPAs fully documented and tracked until completion?	☐	☐	☐
• Are all CAPA actions documented and verified for effectiveness?	☐	☐	☐
• Are CAPA logs updated in real time?	☐	☐	☐
• Are CAPA records reviewed periodically to ensure continual compliance?	☐	☐	☐
• Are historical CAPA records accessible for FDA inspections?	☐	☐	☐
• Are CAPA closure justifications recorded for each case?	☐	☐	☐
• Are completed CAPA records archived with supporting evidence?	☐	☐	☐
• Are CAPA records indexed for easy retrieval during audits?	☐	☐	☐
• Are CAPA records protected from unauthorised changes?	☐	☐	☐
SOP Compliance & Updates			
• Are CAPA SOPs regularly reviewed and updated?	☐	☐	☐
• Are only current SOP versions used during CAPA reviews?	☐	☐	☐
• Are CAPA checklists version controlled and trained upon revision?	☐	☐	☐
• Are changes to CAPA processes documented, approved, and communicated?	☐	☐	☐
• Are CAPA procedures regularly updated based on effectiveness outcomes?	☐	☐	☐
• Are CAPA procedures aligned with regulatory requirements?	☐	☐	☐
• Are specification changes approved, communicated, and trained before implementation?	☐	☐	☐
• Are CAPA documents including impact assessments reviewed and approved by authorised personnel?	☐	☐	☐
• Is there a written procedure for CAPA initiation, documentation, and follow-up?	☐	☐	☐
• Are CAPA-related SOP deviations documented and justified?	☐	☐	☐

II. CAPA Initiation & Planning

	Yes	No	NA
Initiation Criteria & Approvals			
• Is there an automatic CAPA initiation mechanism upon completion of an investigation?			
• Are there clear criteria for initiating a CAPA?			
• Is a CAPA generated for every investigation regardless of the outcome?			
• Are CAPAs initiated for all identified discrepancies?			
• Are CAPA responsibilities clearly defined and documented for all departments?			
• Is management approval documented before CAPA execution?			
• Are CAPA initiation dates recorded and tracked?			
CAPA Action Plan Developmen			
• Are CAPA plans developed based on root cause analysis?			
• Are CAPA action items prioritized based on risk level?			
• Does each CAPA include a detailed evaluation plan for its effectiveness?			
• Are CAPA timelines clearly defined and adhered to?			
• Are ongoing reviews and adaptations included in CAPA plans to address process shifts?			
• Are interim controls identified and implemented before permanent solutions?			
• Are CAPAs developed specifically for each unique root cause identified?			
• Is a CAPA plan followed after every media fill failure?			
• Are preventive action plans created to avoid recurrence of issues?			
• Are CAPA action plans approved by the Quality Unit before execution?			
• Are CAPA plans within the Quality System reviewed to ensure alignment with existing SOPs and regulatory requirements?			
• Are facility or equipment-related CAPAs assessed to confirm corrective actions will not impact other validated systems?			
• Are CAPA actions for material control verified to prevent recurrence of supplier-related deviations?			
• Are production process-related CAPAs validated to ensure changes do not introduce new risks or variability?			

III. CAPA Investigation & Root Cause Analysis

	Yes	No	NA
Investigation Process			
• Has a thorough investigation been conducted for each non-conformance?	☐	☐	☐
• Are CAPA investigations documented and reviewed by the quality team?	☐	☐	☐
• Is there a system for trending and analysis of recurring non-conformances?	☐	☐	☐
• Are all complaints followed by documented CAPA activities?	☐	☐	☐
• Does the CAPA process include evaluation of all potential contributing factors?	☐	☐	☐
• Are multiple departments involved in CAPA investigations?	☐	☐	☐
• Are supplier-related issues included in CAPA investigations?	☐	☐	☐
• Are investigation timelines monitored and tracked?	☐	☐	☐
Root Cause Determination			
• Are CAPAs based on thorough root cause identification?	☐	☐	☐
• Are root causes clearly identified in each CAPA report?	☐	☐	☐
• Are corrective actions addressing the root causes identified investigations?	☐	☐	☐
• Do preventive actions address the root cause and provide long-term solutions?	☐	☐	☐
• Are root causes identified during CAPA generation assessed for recurrence and scope across systems?	☐	☐	☐
• Are analytical tools used to verify the root cause?	☐	☐	☐
• Is root cause analysis conducted for every identified issue?	☐	☐	☐
• Are secondary contributing factors identified and documented?	☐	☐	☐

IV. CAPA Implementation & Monitoring

	Yes	No	NA

Corrective Actions Execution

• Are corrective actions developed and implemented for identified equipment deficiencies?	☐	☐	☐
• Are corrective actions implemented for all critical investigations?	☐	☐	☐
• Are corrective actions tracked and followed up until completion?	☐	☐	☐
• Are corrective actions addressing the root causes of OOS issues?	☐	☐	☐
• Are corrective actions for identified deviations tracked to closure?	☐	☐	☐
• Are corrective actions validated with objective evidence of problem resolution?	☐	☐	☐
• Are corrective actions re-evaluated if similar issues occur again?	☐	☐	☐

Preventive Actions Implementation

• Is there a system in place to ensure preventive actions are taken to avoid recurrence?	☐	☐	☐
• Is there a preventive action plan to avoid recurrence of the issue?	☐	☐	☐
• Are preventive actions implemented and monitored for effectiveness?	☐	☐	☐
• Are preventive actions reviewed for effectiveness periodically?	☐	☐	☐
• Were robust preventive actions established in the CAPA plan to avoid recurrence of defects?	☐	☐	☐
• Is sustainability of preventive actions verified periodically?	☐	☐	☐
• Are CAPA actions promptly initiated in response to identified microbial contamination issues?	☐	☐	☐
• Are CAPA measures effectively addressing identified deviations?	☐	☐	☐
• Are CAPA timelines clearly defined and adhered to?	☐	☐	☐
• Are CAPA actions adequately documented and tracked until completion?	☐	☐	☐
• Are interim control measures implemented until CAPA actions are completed?	☐	☐	☐

V. CAPA Effectiveness Verification

	Yes	No	NA
Effectiveness Checks			
• Is CAPA effectiveness verified after implementation?	☐	☐	☐
• Is the effectiveness of implemented corrective actions regularly monitored?	☐	☐	☐
• Are CAPAs monitored for effectiveness post-implementation?	☐	☐	☐
• Are CAPA effectiveness checks conducted to ensure problem resolution?	☐	☐	☐
• Is effectiveness of CAPA actions verified post-implementation?	☐	☐	☐
• Are follow-up reviews conducted to confirm CAPA effectiveness?	☐	☐	☐
• Are CAPA actions evaluated for effectiveness before closure?	☐	☐	☐
• Are verification criteria defined before CAPA closure?	☐	☐	☐
Continuous Improvement from CAPAs			
• Is the CAPA effectiveness verified through systematic post-implementation testing?	☐	☐	☐
• Are effectiveness checks documented before closing CAPAs?	☐	☐	☐
• Are CAPA effectiveness checks formally scheduled and tracked for completion?	☐	☐	☐
• Is there a process for verifying CAPA effectiveness before product release?	☐	☐	☐
• Is CAPA effectiveness monitored long-term to ensure sustainability?	☐	☐	☐
• Are lessons from CAPA activities integrated into process improvements?	☐	☐	☐
• Are CAPA outcomes reviewed during management reviews?	☐	☐	☐

VI. Risk Assessment & Regulatory Alignment

	Yes	No	NA
Risk Analysis in CAPAs			
• Are mandatory risk assessments included in CAPA processes?	☐	☐	☐
• Are risk assessments conducted during the CAPA process?	☐	☐	☐
• Do CAPAs include risk assessments for potentially impacted products or processes?	☐	☐	☐
• Does the CAPA process include regular risk assessment reviews?	☐	☐	☐
• Are CAPA requirements triggered for repeated or systemic failures?	☐	☐	☐
• Are product quality risks documented and mitigated?	☐	☐	☐
• Are CAPA risk assessments approved before closure?	☐	☐	☐
Regulatory & SOP Compliance			
• Are CAPA procedures followed for all reported complaints?	☐	☐	☐
• Are CAPA procedures updated to include mandatory corrective actions for inspection failures?	☐	☐	☐
• Are CAPA procedures aligned with notification requirements?	☐	☐	☐
• Do CAPA records indicate notification to the Corporate Quality Unit?	☐	☐	☐
• Are CAPAs compliant with applicable GMP and FDA guidelines?	☐	☐	☐
• Is the CAPA process rigorous and does it address root causes comprehensively?	☐	☐	☐
• Are risk assessments conducted for all major deviations linked to CAPAs?	☐	☐	☐
• Are CAPA records maintained in compliance with data integrity requirements?	☐	☐	☐

VII. CAPA Training & Competency Management

	Yes	No	NA
Staff Training on CAPA			
• Are staff regularly trained on comprehensive CAPA implementation?	☐	☐	☐
• Are personnel trained to identify and document CAPA actions correctly?	☐	☐	☐
• Are personnel trained in CAPA processes and root cause analysis?	☐	☐	☐
• Are personnel trained on CAPA procedures regularly?	☐	☐	☐
• Is staff adequately trained on CAPA development and implementation?	☐	☐	☐
• Are CAPA training materials reviewed for accuracy and currency?	☐	☐	☐
• Is CAPA training effectiveness evaluated after sessions?	☐	☐	☐
Specialist Skills & RCA Training			
• Are training sessions conducted for staff on CAPA procedures?	☐	☐	☐
• Are staff trained on the revised CAPA procedures?	☐	☐	☐
• Are personnel trained on CAPA procedures for contamination events?	☐	☐	☐
• Are operators trained on new controls and oversight procedures for parameter adjustments?	☐	☐	☐
• Is training effectiveness evaluated periodically?	☐	☐	☐
• Are CAPA trainers qualified and certified?	☐	☐	☐
• Are Quality Unit personnel trained in comprehensive CAPA documentation?	☐	☐	☐
• Are lessons from CAPA investigations integrated into future training?	☐	☐	☐

VIII. CAPA Trending, Analysis & Reporting

	Yes	No	NA
CAPA Trend Analysis			
• Is there a system for trending and analysis of recurring CAPA issues?	☐	☐	☐
• Are trends in CAPA issues identified in real-time?	☐	☐	☐
• Does CAPA closure include documented trend assessments?	☐	☐	☐
• Are CAPA effectiveness reviews conducted per SOP-defined intervals?	☐	☐	☐
• Is CAPA data trended and analyzed for systemic process changes?	☐	☐	☐
• Are CAPA trends shared in management review meetings?	☐	☐	☐
• Are CAPA trend reports generated periodically?	☐	☐	☐
CAPA Performance Reporting			
• Are CAPA actions tracked and documented until completion?	☐	☐	☐
• Are CAPA outcomes tracked and analyzed for effectiveness?	☐	☐	☐
• Are CAPA failures tracked as a KPI?	☐	☐	☐
• Are CAPA delays escalated to senior management?	☐	☐	☐
• Are CAPA performance metrics shared with stakeholders?	☐	☐	☐
• Are CAPA status reports issued regularly?	☐	☐	☐
• Is trending data used effectively in forming CAPA plans?	☐	☐	☐
• Are recurring CAPA issues analyzed for systemic process improvements?	☐	☐	☐
• Are CAPA performance dashboards maintained and reviewed?	☐	☐	☐

IX. CAPA Governance & Audit Readiness

	Yes	No	NA
Internal CAPA Audits			
• Is there a regular audit process to ensure CAPA compliance?	☐	☐	☐
• Are periodic audits performed to ensure CAPA compliance?	☐	☐	☐
• Are periodic audits conducted to ensure CAPA documentation compliance?	☐	☐	☐
• Are CAPA actions audited for compliance and effectiveness?	☐	☐	☐
• Are mock audits of CAPA systems conducted?	☐	☐	☐
• Are audit findings linked to CAPA initiation?	☐	☐	☐
CAPA Oversight & Governance			
• Is there an effective CAPA management system in place?	☐	☐	☐
• Are CAPAs implemented and documented in a timely manner?	☐	☐	☐
• Is there a system in place to flag and review overdue CAPAs?	☐	☐	☐
• Is senior management involved in CAPA oversight?	☐	☐	☐
• Are CAPA governance structures reviewed for efficiency?	☐	☐	☐
• Are CAPA steering committees established for oversight?	☐	☐	☐
• Are CAPA activities regularly reviewed and effectiveness assessed?	☐	☐	☐
• Are CAPA closure decisions documented and justified?	☐	☐	☐
• Are audit results used to improve CAPA processes?	☐	☐	☐

	Yes	No	NA
• Are CAPA governance responsibilities clearly assigned and documented?	☐	☐	☐
• Are lessons learned from CAPA audits integrated into SOP updates?	☐	☐	☐
• Are CAPA metrics reviewed during annual quality reviews?	☐	☐	☐