Leucine

Investigation

Audit Readiness Checklist

I. Investigation Governance & Oversight (IGO)

	Yes	No	NA
Investigation Policy & SOP (Standard Operating Procedure) Adherence			
• Are all investigation SOPs current, approved, and controlled in the quality management system (QMS)?	☐	☐	☐
• Are investigation SOPs aligned with FDA, EMA, and ICH Q10 guidelines?	☐	☐	☐
• Are SOP updates communicated promptly to all relevant staff?	☐	☐	☐
• Is there documented training for all personnel on updated investigation SOPs?	☐	☐	☐
• Are SOP changes linked to lessons learned from previous investigations?	☐	☐	☐
• Is there an annual review of investigation policies by the Quality Unit (QU)?	☐	☐	☐
• Are SOP deviations documented and justified during investigations?	☐	☐	☐
Investigation Roles, Accountability & Authority			
• Is a qualified investigation lead assigned for each case?	☐	☐	☐
• Are QA (Quality Assurance) reviewers independent of operational teams?	☐	☐	☐
• Are SMEs (Subject Matter Experts) involved where technical expertise is required?	☐	☐	☐
• Are investigation signatories documented in the quality system?	☐	☐	☐
• Are training records for investigators complete and current?	☐	☐	☐
• Are periodic capability assessments of investigators performed?	☐	☐	☐
• Are backup investigators designated to ensure continuity during prolonged or complex investigations?	☐	☐	☐
• Are investigation roles and responsibilities clearly defined in SOPs?	☐	☐	☐
• Is there a documented process to resolve conflicts in investigation findings between different stakeholders?	☐	☐	☐

II.Deviation & Incident Investigation Process (DIIP)

	Yes	No	NA
Deviation Capture & Classification			
• Are all deviations recorded in the eQMS (Electronic Quality Management System)?	☐	☐	☐
• Are deviations classified as minor, major, or critical based on impact?	☐	☐	☐
• Is there immediate escalation of critical deviations to QA leadership?	☐	☐	☐
• Are deviation forms complete, with all fields filled in before closure?	☐	☐	☐
• Is there trend analysis for recurring deviations?	☐	☐	☐
• Are deviations linked to associated CAPAs (Corrective and Preventive Actions)?	☐	☐	☐
• Is deviation data reviewed in periodic management review meetings?	☐	☐	☐
Root Cause Analysis (RCA)			
• Is RCA methodology (e.g., 5 Whys, Fishbone) documented and followed?	☐	☐	☐
• Are RCAs evidence-based rather than assumption-based?	☐	☐	☐
• Are systemic issues identified and documented during RCA?	☐	☐	☐
• Are multiple hypotheses explored before determining the root cause?	☐	☐	☐
• Is RCA training provided annually to investigation teams?	☐	☐	☐
• Are RCA conclusions supported with raw data and trend reports?	☐	☐	☐
• Are RCA results reviewed and approved by the Quality Unit?	☐	☐	☐

III. Quality Result Investigations

Out of Specification (OOS) Management			
• Are OOS results reported to QA within one working day?	☐	☐	☐
• Is there a defined Phase I (laboratory) and Phase II (full-scale) OOS process?	☐	☐	☐
• Are retests scientifically justified and documented?	☐	☐	☐
• Are batch dispositions held until OOS closure?	☐	☐	☐

	Yes	No	NA
Out of Trend (OOT) Management			
• Is OOT trending conducted for stability and in-process data?	☐	☐	☐
• Are OOT investigations conducted with the same rigor as OOS?	☐	☐	☐
• Is statistical analysis used to identify OOT events?	☐	☐	☐
• Are OOT results linked to process capability evaluations?	☐	☐	☐
• Is OOT training included in analyst onboarding?	☐	☐	☐
• Are OOT findings escalated if linked to product quality risk?	☐	☐	☐
• Are OOT procedures reviewed annually for relevance?	☐	☐	☐

IV. Environmental Failures

Environmental Excursion Investigations			
• Are environmental monitoring excursions documented in the EM (Environmental Monitoring) system?	☐	☐	☐
• Are root causes traced to facility or personnel activities?	☐	☐	☐
• Are excursions linked to CAPA actions?	☐	☐	☐
• Is trend analysis performed for microbial and particulate data?	☐	☐	☐
• Are room classifications revalidated after major excursions?	☐	☐	☐
• Is EM data reviewed during quarterly quality reviews?	☐	☐	☐
Product Contamination Investigations			
• Are contamination incidents investigated immediately?	☐	☐	☐
• Are contamination sources confirmed with laboratory evidence?	☐	☐	☐
• Is batch release withheld pending contamination investigation closure?	☐	☐	☐
• Are contamination investigations extended to supplier materials if relevant?	☐	☐	☐
• Is cleaning validation reviewed after contamination events?	☐	☐	☐
• Are contamination cases trended to identify repeat issues?	☐	☐	☐

V. Complaint & Adverse Event Investigations (CAEI)

	Yes	No	NA
Complaint Handling			
• Are complaints logged in the complaint management system (CMS)?	☐	☐	☐
• Are complaint investigations initiated within defined timelines?	☐	☐	☐
• Are batch records reviewed for every complaint?	☐	☐	☐
• Are complaints classified by severity and risk category?	☐	☐	☐
• Are complaint investigation outcomes linked to product disposition?	☐	☐	☐
• Are complaint trends reviewed during management review meetings?	☐	☐	☐
• Are complaint investigations cross-checked with deviation records?	☐	☐	☐
Adverse Event Investigation			
• Are adverse events (AEs) reported to pharmacovigilance (PV) within regulatory timelines?	☐	☐	☐
• Are safety signal investigations coordinated with PV teams?	☐	☐	☐
• Are CAPAs linked to AE investigations?	☐	☐	☐
• Is medical review conducted for serious AEs?	☐	☐	☐
• Are AE investigations trended for recurrence?	☐	☐	☐

VI. CAPA Effectiveness & Follow-up (CEF)

	Yes	No	NA
CAPA Implementation			
• Are CAPAs linked to investigation root causes?	☐	☐	☐
• Are interim controls implemented until CAPA closure?	☐	☐	☐
• Are CAPA timelines monitored for adherence?	☐	☐	☐
• Are CAPA delays justified and documented?	☐	☐	☐
• Is CAPA status reviewed in monthly QA meetings?	☐	☐	☐
• Are CAPAs linked to preventive maintenance programs where relevant?	☐	☐	☐
• Are CAPA priorities aligned with risk assessment outcomes?	☐	☐	☐
Effectiveness Verification			
• Is there a documented CAPA effectiveness verification process?	☐	☐	☐
• Are effectiveness checks performed within defined timeframes?	☐	☐	☐
• Is recurrence data reviewed to confirm CAPA success?	☐	☐	☐
• Are failed CAPAs re-opened for further action?	☐	☐	☐
• Are CAPA results communicated to all impacted departments?	☐	☐	☐
• Are CAPA KPIs (Key Performance Indicators) tracked?	☐	☐	☐
• Are CAPA learnings integrated into SOP updates?	☐	☐	☐

VII. Quality Trends & Metrics

Metrics & Trending			
• Are investigation closure timelines tracked and trended?	☐	☐	☐
• Is investigation backlog reported to senior management?	☐	☐	☐
• Are repeat deviations analyzed for systemic issues?	☐	☐	☐
• Are investigation outcomes trended by root cause category?	☐	☐	☐
• Are periodic KPI reports generated for investigations?	☐	☐	☐
• Is investigation data used in annual product quality reviews (APQR)?	☐	☐	☐

	Yes	No	NA
Continuous Improvement			
• Are investigation lessons learned documented in a shared repository?	☐	☐	☐
• Are case studies from past investigations used in training?	☐	☐	☐
• Are investigation procedures revised based on trend data?	☐	☐	☐
• Is there a program for cross-site sharing of investigation best practices?	☐	☐	☐
• Are periodic internal audits performed on investigation quality?	☐	☐	☐
• Are investigation effectiveness surveys conducted with investigators?	☐	☐	☐
• Are improvement actions tracked to closure?	☐	☐	☐
• Are investigation systems benchmarked against industry best practices?	☐	☐	☐
• Is there a documented plan for continual enhancement of investigation systems?	☐	☐	☐
• Are root cause analysis tools periodically evaluated for effectiveness and updated as needed?	☐	☐	☐
• Are investigation outcomes analyzed to identify recurring issues across multiple sites or departments?	☐	☐	☐
• Is investigator training content updated based on recent regulatory inspection findings?	☐	☐	☐
• Are corrective and preventive actions (CAPAs) from investigations verified for sustained effectiveness?	☐	☐	☐
• Is there a formal review process to integrate regulatory guidance updates into investigation procedures?	☐	☐	☐