Leucine

Deviation Management

Audit Readiness Checklist

I. DOCUMENTATION

	Yes	No	NA
Deviation Procedures			
• Are there documented procedures for managing deviations?	☐	☐	☐
• Are procedures easily accessible to relevant personnel?	☐	☐	☐
Deviation Reports			
• Are all deviations recorded promptly and accurately?	☐	☐	☐
• Do deviation reports include detailed descriptions of the deviation, including time, date, and involved personnel?	☐	☐	☐
Investigation Records			
• Are root cause analyses conducted for all deviations?	☐	☐	☐
• Are investigation records complete and thorough?	☐	☐	☐
CAPA Documentation			
• Are corrective and preventive actions (CAPA) identified and implemented for each deviation?	☐	☐	☐
• Are CAPA records documented and reviewed regularly?	☐	☐	☐

II. PROCESS AND SYSTEM REVIEWS

	Yes	No	NA
Deviation Review			
• Are deviations reviewed by a designated quality control unit?	☐	☐	☐
• Are deviations categorized based on severity and impact?	☐	☐	☐

	Yes	No	NA
Root Cause Analysis			
• Are root cause analyses conducted using standardized methods (e.g., Fishbone, 5 Whys)?	☐	☐	☐
• Are findings from root cause analyses documented and approved?	☐	☐	☐
Training			
• Are personnel trained on deviation handling and investigation procedures?	☐	☐	☐
• Are training records current and complete?	☐	☐	☐

III. REGULATORY COMPLIANCE

	Yes	No	NA
Regulatory Guidelines			
• Are deviations evaluated for compliance with relevant regulatory guidelines (FDA, EU GMP, WHO GMP, etc.)?	☐	☐	☐
• Are regulatory bodies notified of significant deviations as required?	☐	☐	☐
Quality Risk Management			
• Are deviations integrated into the quality risk management system?	☐	☐	☐
• Are risks associated with deviations documented and managed?	☐	☐	☐

IV. FACILITY AND EQUIPMENT

	Yes	No	NA
Equipment Deviations			
• Are deviations related to equipment documented and evaluated?	☐	☐	☐
• Are calibration and maintenance records updated to reflect deviation findings?	☐	☐	☐
Facility Deviations			
• Are deviations related to the facility documented and evaluated for impact on product quality and compliance?	☐	☐	☐

V. COMMUNICATION AND COORDINATION

Deviation Management Team Preparation			
• Is the deviation management team aware of their roles and responsibilities?	☐	☐	☐
• Are relevant stakeholders involved in the deviation management process?	☐	☐	☐
Deviation Review Meetings			
• Are regular meetings held to review and discuss deviations?	☐	☐	☐
• Are meeting minutes documented and actions tracked?	☐	☐	☐
Pre-Audit Review			
• Is a pre-audit review conducted to ensure deviation management readiness?	☐	☐	☐
• Are potential issues identified and addressed before the audit?	☐	☐	☐

VI. FOLLOW-UP AND MONITORING

	Yes	No	NA
Post-Implementation Review			
• Are deviations reviewed after investigation to ensure they are resolved?	☐	☐	☐
• Is there documented evidence of the review and its findings?	☐	☐	☐
Monitoring and Reporting			
• Are deviations monitored to ensure CAPA effectiveness?	☐	☐	☐
• Are recurring deviations analyzed for patterns and trends?	☐	☐	☐
Continuous Improvement			
• Are lessons learned from deviations documented and used for continuous improvement?	☐	☐	☐
• Are deviation management procedures reviewed and updated based on audit findings?	☐	☐	☐