

Computerized Systems Validation – Audit Trail Review Execution

Our expert team meticulously reviews Computerized System’s Audit Trails, focusing on key aspects such as post-change assessments, user roles, access management controls, and project or method modifications. We prioritize compliance with FDA requirements to safeguard data integrity and uphold regulatory standards

Audit Trail Data Analysis

Our team conducts comprehensive reviews of Audit Trail data, meticulously analyzing critical events with potential impact on Quality and Safety of batches, system changes, access management activities, and project/method modifications. We scrutinize Audit Trail entries to ensure adherence to FDA regulations, assess data integrity, and identify any anomalies or deviations that may indicate unauthorized access or data manipulation.

Compliance Verification

We verify compliance with FDA regulations and guidelines pertaining to audit trail management. This involves assessing the completeness, accuracy, and reliability of audit trail data to ensure it captures all relevant system activities and meets regulatory requirements outlined in FDA's 21 CFR Part 11 and other relevant guidance documents. Our team evaluates system configurations, user permissions, and data retention practices to mitigate risks and maintain compliance.

Risk Assessment and Mitigation

We conduct risk assessments based on Audit Trail review findings to identify potential vulnerabilities or areas of non-compliance within the computerized system. We assess the impact of audit trail discrepancies on data integrity, product quality, and regulatory compliance. Our experts develop risk mitigation strategies, implement corrective actions, and enhance system controls to address identified issues and prevent recurrence, thereby ensuring the reliability and accuracy of audit trail data.

