

Computerized System Validation Audit Readiness – Audit Execution

We conduct thorough preparation audits to evaluate your current status of CSV activities, identify opportunities of improvement, and develop comprehensive CAPA plans to address any GAPS. Our expert team then closely monitors the execution of CAPA plans, providing ongoing support and guidance to ensure full compliance and readiness for official audits

Audit Preparation and Execution

Our consultants conduct a comprehensive review of your computerized systems validation (CSV) processes, including documentation, procedures, and system configurations.

We perform on-site audits to verify the implementation and effectiveness of your CSV activities, ensuring alignment with regulatory requirements. Detailed analysis is carried out to identify any discrepancies between current practices and regulatory standards, highlighting areas for improvement.

CAPA Plan Development

We compile audit findings and categorize them based on severity and impact on compliance. Our experts work closely with your team to develop customized Corrective and Preventive Action (CAPA) plans, outlining specific actions to address identified deficiencies. Each CAPA is prioritized based on risk assessment, and a realistic timeline is established for completion to ensure timely resolution of compliance issues.

CAPA Plan Follow-up and Monitoring

We provide guidance and support throughout the implementation phase, assisting in the execution of CAPA activities and overcoming any challenges encountered.

Regular monitoring of CAPA plan progress is conducted to ensure adherence to timelines and milestones. Completed CAPA activities are thoroughly reviewed, documented, and verified for effectiveness, with proper documentation maintained for regulatory purposes.

