

Computerized Systems Validation – Periodic Review Execution

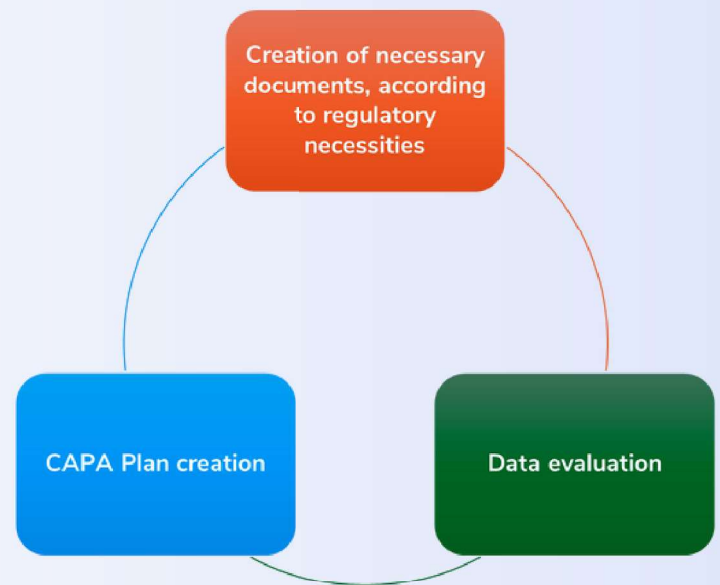
Our expert consultants conduct the necessary Periodic Reviews of validated computerized systems to ensure ongoing compliance with regulatory requirements and industry standards. We assist clients in maintaining the integrity, reliability, and security of their systems through regular assessments and updates

System Change Analysis

We conduct a detailed examination of relevant changes made (directly and indirectly) to the computerized system since the last review cycle, including software updates, configuration modifications, data migrations, and other alterations impacting system functionality or regulatory compliance. Our team assesses the impact of changes on validation status, ensuring that appropriate validation activities are executed to maintain CSV status.

IT Infrastructure Qualification Assessment

Our experts evaluate the qualification status of the IT infrastructure supporting the computerized system. This involves reviewing qualification documents related to servers, networks, databases, and other infrastructure components. We verify compliance with regulatory requirements, assess the effectiveness of qualification activities, and identify any GAPS or deficiencies requiring corrective action to uphold system reliability and compliance.



Supplier and Service Provider Evaluation

Comprehensive assessment of suppliers and service providers associated with the computerized system (e.g.: software vendors, hardware suppliers, maintenance providers). Our evaluation encompasses supplier qualification status, adherence to contractual agreements, responsiveness to corrective actions, and overall quality of products or services delivered.



- Quality Consulting and Risk Management
- Qualification and Validation
- Personnel Qualification
- Customer-specific provision of QMS