Computerized Systems Validation Landscape – GAP Assessment

We conduct a detailed evaluation of the client's existing CSV framework, including VMP, SOPs, IT infrastructure, and document templates, to identify potential GAPs or deficiencies in compliance with FDA, EMA, and GAMP5 regulations. This assessment aims to ensure that the company's CSV processes align with industry standards and regulatory requirements, mitigating risks and enhancing overall compliance posture

Background Documentation Review

Our team meticulously examines the client's CSV background, like SOPs and all relevant documents, to assess their adequacy and alignment with regulatory guidelines.

We identify any discrepancies or GAPs in the documentation, such as missing steps, outdated records, or inconsistencies in content, to form the basis of our GAP analysis.

Evaluation of Documents

Infrastructure Assessment

We evaluate the client's IT Infrastructure Qualification, to determine its suitability for supporting CSV activities, including considerations such as system architecture, data integrity measures, and cybersecurity protocols.

This assessment helps identify potential vulnerabilities or deficiencies in the IT infrastructure that may impact the integrity and compliance of computerized systems.

Infrastructure Evaluation

CAPA Plan Creation

Templates Evaluation

Our experts review the client's document templates used for CSV activities to ensure they meet regulatory requirements and industry best practices.

We assess the comprehensiveness, accuracy, and consistency of templates such as URS, Risk Assessments, Traceability Matrix, and Protocols to optimize their effectiveness in supporting the validation process.

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

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