

Computerized Systems Validation Landscape – Implementation or Improvement

Our expert consultancy provides comprehensive technical support to create from scratch or improve the CSV Landscape, including the development of policies, SOPs, and executional templates, to ensure alignment with international regulations (e.g.: FDA, EMA, and GAMP5) and industry best practices

Reference selection and GAP Analysis

Based on the necessary references, our team conducts a comprehensive assessment of the current CSV landscape (if applicable) within the client's organization.

We review existing documentation, including validation protocols, SOPs, and system configurations, to identify GAPs and areas of non-compliance. Through meticulous analysis, we pinpoint specific deficiencies that need to be addressed to ensure alignment with international regulations and industry standards.

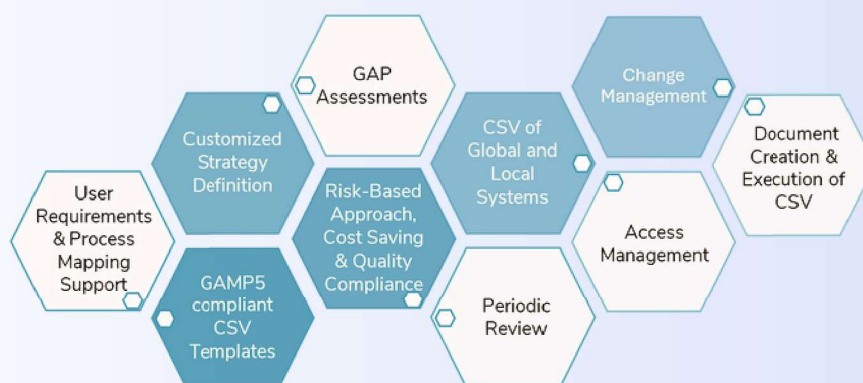
Strategy Development and Documentation

Based on the findings of the GAP analysis, we collaborate closely with the client to develop a tailored CSV strategy. This strategy encompasses the creation of detailed policies, SOPs, and executional templates that outline the necessary procedures and protocols for CSV activities. Our experts ensure that the documentation is aligned with regulatory requirements and best practices, providing a solid framework for the implementation or improvement of CSV processes.

Training and Capacity Building

We promote training sessions and workshops designed to empower personnel involved in CSV activities. Training covers various aspects, including regulatory compliance, risk management principles, validation methodologies, and documentation practices.

By enhancing the knowledge and skills of staff members, we facilitate the effective execution of CSV activities and foster a culture of compliance within the organization.



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

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