Computerized Systems Validation Landscape – Operational Documents Creation

Providing essential templates for executing CSV activities in accordance with FDA, EMA, and GAMP5 requirements, we deliver a comprehensive set of documents, including User Requirement Specifications (URS), Risk Assessments, Traceability Matrix, Protocols and Reports related to all Validation steps (e.g.: IQ, OQ, and PQ)

Customized Template Development

Our experts conduct a comprehensive assessment of the client's systems and processes to identify specific requirements and potential risks.

Based on this assessment, we tailor templates for each operational document to ensure they address the unique needs of the client's systems and comply with regulatory guidelines.

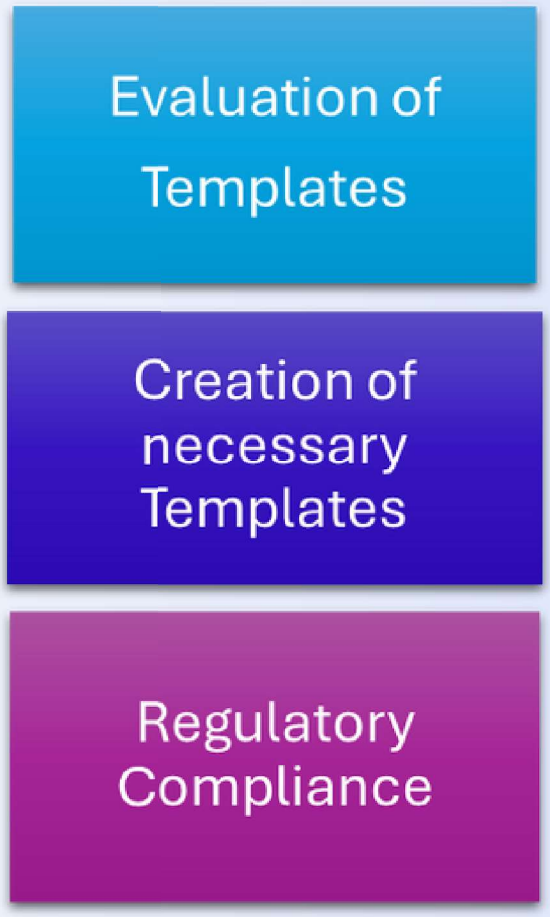
These customized templates are designed to capture all relevant information effectively, facilitating a structured approach to CSV execution while minimizing the risk of oversights or compliance GAPs.

Validation Protocol and Report Templates

Our team provides a range of standardized templates for validation protocols and reports, covering all stages of the validation lifecycle.

These templates are meticulously crafted to include sections for essential details such as system specifications, testing procedures, acceptance criteria, and results documentation.

By leveraging these pre-defined templates, clients can expedite the preparation of validation documentation while ensuring consistency and compliance with regulatory requirements across all validation activities.



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

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