



RC-VLM

VALIDATION LIFECYCLE MANAGEMENT

The Rescop RC-VLM solution provides the tools required to perform system validation of systems in an efficient, controlled and reproducible manner. The solution efficiently manages all types of validation activities, including, equipment, instruments, computer systems, manufacturing lines, and process validation. RC-VLM covers the entire validation lifecycle and is provided using proven technology which is available, rapidly deployed and available via a secure and validated cloud solution.

Objective

Manage and support development, engineering, implementation, validation, qualification and commissioning of automated systems to ensure compliance with GxP regulations and company procedures.

Main functionality

- Integrated Project Management
- Generate an appropriate validation/qualification/commissioning approach for a given system, based on a configurable work flow
- Integrated Risk Management
- Dashboard providing an overview on the validation/qualification/commissioning process and access to the corresponding documents
- Document and version management
- Automated workflow for generation, review and approval of documents
- Content management, incl
 - Definition and linking of requirements, risk items and test cases
 - Possibility to manage content of templates and deliverables in MS Word
- Integrated requirement and test management
- Library for definition and inheritance of default requirements and test scripts
- Design Assistance
 - View documents of similar systems
 - Import requirements and test scripts from existing documentation or library
- Supplier Assessment & Selection

- Automated Traceability Matrix
- Test registration (incl. documented evidence) and defect handling
- Change Control, incl. version management for software
- Leverage previous Qualification Documentation to ensure best practice and avoid starting from a blank page every time
- Email alerts ensure activities are completed on time and escalation email alerts provide you with immediate visibility of any overdue tasks

Benefits

- GxP compliant validation/qualification/commissioning
- Centrally and readily retrievable documentation
- Efficient document review and approval through automated workflow
- Consistent and adequate validation/qualification/ commissioning through standardisation of approach, documentation and content
- Speeding up of the validation/qualification/ commissioning process through reuse of content
- In control through automated and central management reporting
- Paperless validation and compliance
- 21 CFR part 11 and Eudralex Annex 11 ready

Information?

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