

Validation, Qualification and Commissioning (RC-SDLC)

RC-SDLC

Objective

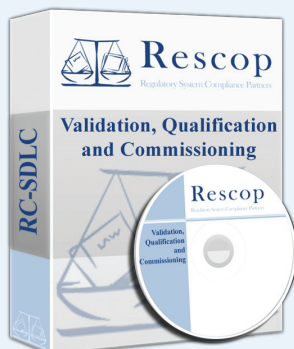
Manage and support development, engineering, implementation, validation, qualification and commissioning of automated systems to ensure compliance with GxP regulations and company procedures.

Main functionality

- Integrated Project Management
- Generate an appropriate validation/qualification/commissioning approach for a given system, based on configurable workflow
- Integrated Risk Management
- Dashboard providing an overview on the validation/qualification/commissioning process and access to the corresponding documents
- Content management, incl. integrated requirement and test management
- Library for definition and inheritance of default requirements and test scripts
- Automated workflow for generation, review and approval of documents
- 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
- Management Reporting

Advantages

- 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 standardization of approach, documentation and content
- Speeding up of the validation/qualification/commissioning process through reuse of content
- Paperless compliance
- 21 CFR part 11 and Eudralex Annex 11 ready



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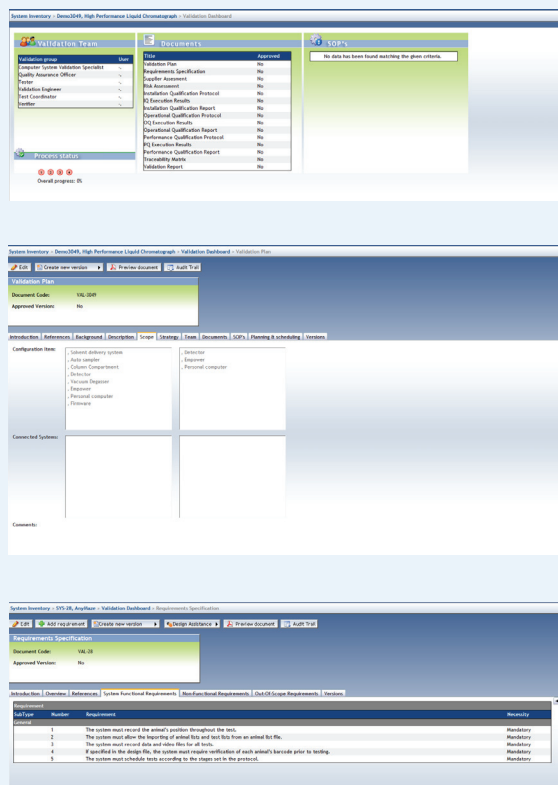
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Rescop also offers other innovative software products:

- Document Management System (RC-DMS)
- Exception Handling and CAPA (RC-CAPA)
- Training Management System (RC-Training)
- Change Management System (RC-Change)
- System Management and Electronic Logbook (RC-Logbook)
- Automation Compliance Management Suite (RC-ACMS)