

System Management and Electronic Logbook (RC-Logbook)

RC-Logbook

Objective

Management of automated systems and registration in a GxP compliant electronic logbook.

Main functionality

- Register automated systems, incl. use and compliance status
- Configurable system overviews
- Register system components, incl. hardware, software, equipment, documentation and users
- Baseline reporting
- Supplier management
- Scheduling of activities
- Automated generation and assignment of tasks
- Notifications and alerts (incl. escalation) by e-mail
- Monitor the execution of activities
- Registration of activities in electronic logbook
- Approval of results
- Definition of default activity recurrences and frequencies per system type
- Trend reporting
- Management Reporting

Advantages

- GxP compliant system overviews
- In control through an overview on the company's systems and their compliance status
- Full traceability of all configuration changes during the total lifecycle of systems
- Permanent inspection readiness through scheduling and automated generation of tasks (incl. notifications and alerts)
- Centrally and readily retrievable logbooks
- Standardization of logbook information
- Consistency through definition of default activity recurrences and frequencies per system type
- Paperless compliance
- 21 CFR part 11 and Eudralex Annex 11 ready



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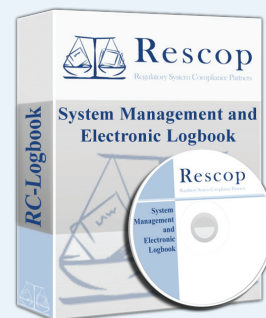
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