CERDAAC
Compliance Module

SIMCO

SIMCO's CERDAAC® cloud-based quality execution system is widely used by leading life science organizations to reduce costs and improve operations. Its Compliance Module provides powerful features to help these organizations comply with FDA regulations.

Business Challenge

How do you ensure your asset management system is compliant with FDA guidelines?

CERDAAC Compliance Module

- CERDAAC's Compliance Module complies with the industry's most stringent quality guidelines
- Validated to cover FDA 21 CFR Part 11 (electronic records, electronic signatures) and relevant Part 820 (quality system regulation) requirements
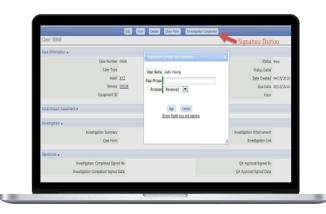
FEATURES AND BENEFITS

Validation

- Evidence of validation covering FDA 21 CFR Part 11 and relevant Part 820 requirements is provided to Compliance Module customers
- SaaS validated software eliminates or reduces the need for customers to invest in their own software validation efforts
- Each software release is validated by SIMCO

Digital Signatures

- Can be applied throughout CERDAAC software solutions
- Uses cryptographic authentication methods to verify identity of signer and integrity of data
- Maintains audit trails, non-repudiation safeguards, and two identification components such as identification code (username) and password as required by FDA Part 11
- Signatures are role based and signature button is only available for configured roles
- Record can have multiple levels of signatures
- Each signature can lock down fields on individual record, so when a field is modified, the signature is invalidated, and changes are captured in the audit log
- Configured by SIMCO Professional Services
- SIMCO certificates can be digitally signed by SIMCO Technicians and QA Inspectors

Digital Signatures streamline the approval process

Alerts and Notifications

- Alerts (triggered notifications) can be created based on digital signatures
- Chain-of-command alerts and escalations
- Compliance-related alerts and reports

Dashboards & Reports

- Executive dashboards display real-time program KPIs for decision making
- Extensive pre-built reports to uncover program bottlenecks and streamline operations
- Report builder for personalized analytics
- Automate knowledge dissemination through report scheduling, email, and export.

Audit Support

Compliance module includes 4 hours of SIMCO validation/verification audit support

More Information and Demonstration:

- Call +1-866-299-6029
- Email hello@simco.com