CERDAAC
Case Management

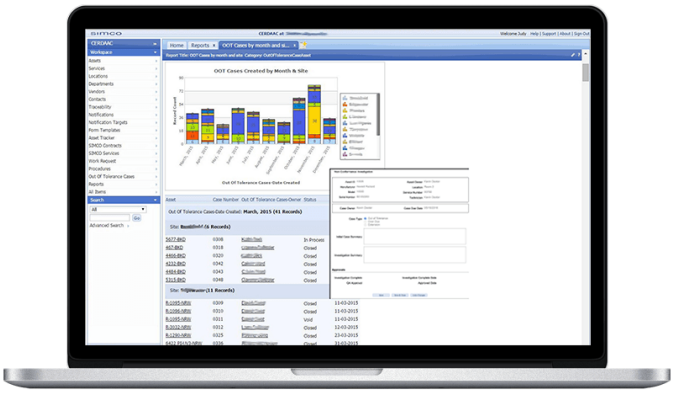
SIMCO's CERDAAC® cloud-based quality execution system is widely used by leading life science and technology organizations to reduce costs and improve operations. It provides quality teams with powerful features to manage out of tolerance cases and non-conformance reports.

Business Challenge

How do you ensure regulatory and corporate compliance by documenting out of tolerance (OOT) conditions and tracking non-conformance reports (NCR) to closure and signoff?

CERDAAC Case Management Solution

- Automatically generate cases and alert users of OOTs and non-conformances
- eForms deliver complete documentation
- Digital signatures ensure review / compliance



OOT Cases by site/month and documented in eForms

FEATURES AND BENEFITS

CAPA Automation & Case Management:

- Properly implemented corrective and preventive action (CAPA) improves product quality and ensures compliance with regulatory standards.
- Designed to manage Out of Tolerance (OOT) cases and other non-conformant service conditions, eForms makes your job easier by automating the CAPA process, connecting those processes with other quality procedures, and significantly reducing the time spent executing your CAPA program.
- Digital solution reduces risk of lost or incomplete data, preventing costly delays.
- An OOT Case is a repository for managing resolution workflow for each OOT asset and provides a tracking mechanism that facilitates OOT resolution separate from normal service tracking.
- The OOT Cases page displays a list of current and historical cases.
- Milestone Dates, On-Time Status, & customer defined Days to Close are maintained and used to manage timely case resolution.
- Configurable Case creation is based on any non-conformant instrument status.

Notifications & Escalations:

- Chain-of-command alerts and escalations ensure process compliance.
- Alerts (triggered notifications) can be created based on digital signatures and events.

Digital Signatures:

- Uses cryptographic authentication methods to verify the identity of the signer and the integrity of the data.
- Maintains audit trails, non-repudiation safeguards, and two identification components such as identification code (user name) and password as required by FDA 21 CFR Part 11.

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.

More Information and Demonstration:

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