



CERDAAC Product Traceability Cloud



The cost of quality represents 12 to 18% of total industry revenue for medical device manufacturers

– McKinsey & Company

Business Challenge

When a television, mobile phone, or pair of shoes fails due to poor quality, the manufacturer often incurs a financial penalty in the form of product return and/or replacement. Significant or widespread product quality issues can damage the company brand and impact customer loyalty. However, for manufacturers in heavily regulated industries like life sciences or defense, product quality has a significantly larger impact. One of the reasons that these industries are so regulated is that their products are used in lives-at-stake applications. In these industries, poor product quality can result in serious injury or death, resulting in financial penalties so significant that companies are forced out of business. Because of these significant risks, product quality and regulatory compliance are often the highest priority items for life science and defense manufacturers.

Product Quality Excellence

CERDAAC Product Traceability Cloud helps quality teams manage product quality and compliance. Digitalizing quality processes like incoming, in-line, and final inspections, streamlines operations and facilitates secure and comprehensive product documentation. Digitalizing also enables automated routing, notification, escalation, and approvals of all forms. With CERDAAC, quality teams can eliminate time spent chasing signatures and approvals on forms and focus their efforts on maintaining product quality and compliance. In the event of a product field failure, CERDAAC has a unique function that allows manufacturers to identify products impacted by a non-conformance of manufacturing equipment. In lives-at-stake industries, shortening the time to notify customers, or time to initiate product recall, can be the difference in a manufacturer's success or failure. CERDAAC Product Traceability Cloud digitizes quality control processes and minimizes risk associated with product quality. Features include:

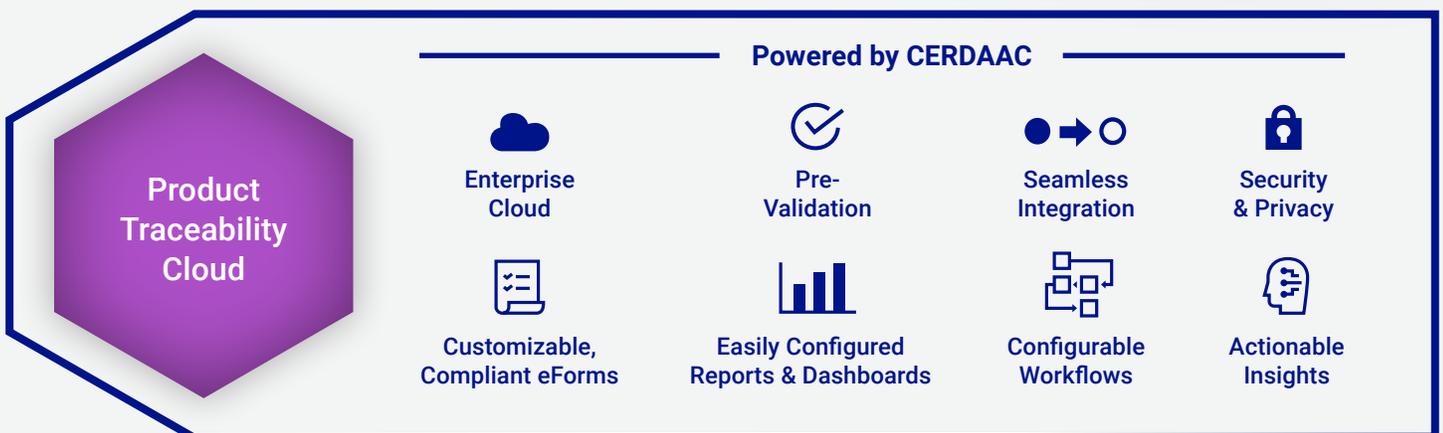
- Ensure traceability between manufacturing equipment and manufactured goods
- Quickly identify products impacted by out-of-tolerance production and test equipment
- Create and manage custom digital checklists for inspections
- Automated routing, notification, escalation and approval of inspection forms
- Easily find and attach inspection data to non-conformance and CAPA processes
- Generate and digitally archive Certificates of Analysis (CoA) or Certificates of Conformance (CoC)
- Secure repository for Quality control documentation (sampling plans, inspection procedures, SOPs, etc)
- Manage Electronic Device History Records (eDHR) for compliance with FDA – 21CFR 820.184
- Comprehensive and searchable audit trails
- Robust and configurable dashboards and reporting
- Unlimited users for increased adoption and scalability

Digitize
Quality Control

Streamline
Product
Inspections

Ensure
Product
Traceability

Regulated Operations
Excellence Matrix



Regulated Ops Excellence

CERDAAC is a connected suite of digital solutions to ensure compliance and maximize profitability



CERDAAC is a highly configurable regulated operations excellence platform that automates and coordinates calibration, maintenance, validations, and other processes to ensure compliance with greater efficiency and less downtime. Trusted by thousands of organizations worldwide, CERDAAC is purpose-built for highly regulated manufacturers who need to deliver high quality products and profits while meeting complex regulatory requirements.

- Native cloud, managed by SIMCO, powered by Google
- Enterprise grade, scalable, and extensible
- Easily tailored forms, notifications, workflows, reports
- Purpose-built for highly regulated manufacturers
- Pre-validated to comply with FDA 21 CFR part 11
- Single, unified, intelligent system of record
- Seamless integration with other systems of record
- Supported by 300+ lean operations experts

Let's talk about how CERDAAC can assist you on your operations and quality digital transformation journey

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