

Life Sciences Review

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SIMCO Electronics

Ensuring Regulatory Readiness for Life Sciences Leaders

For over 60 years, SIMCO Electronics, Inc. has been the forerunner in providing lean quality and compliance expertise, software, and services to manufacturers in the life sciences, aerospace, defense, and other highly regulated industries. Initially founded out of NASA to provide calibration and repair services for test and measurement equipment, today SIMCO has expanded its offerings to include a full suite of regulatory cloud software and services that its customers use to manage the quality and compliance of lifesaving equipment, people and programs.

SIMCO's industry leadership is built on its decades of expertise delivering over 15 million services to more than 3,000 highly regulated customers, including 16 of the top 20 global life sciences companies. In addition to its industry expertise, half of SIMCO's employees have Lean Six Sigma training. "We don't compromise on quality, and we lead by being lean," says Sam Klooster, Vice President of SIMCO's software business. "At the heart of our mission is the understanding that our customers' equipment is used in the most demanding environments to protect the lives of patients, soldiers and loved ones."



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SIMCO's decades of experience in industries that answer to multiple regulatory bodies, such as the FDA, ISO and CLIA, give the company firsthand insight into its customers' unique challenges. To demonstrate regulatory compliance, these manufacturers need clear visibility into how and where each asset is used, maintained and serviced. They also must ensure that the systems used to manage quality are compliant with the FDA's 21 CFR Part 11 and Part 820 regulations. Many struggle with error-prone manual processes that make it difficult to respond effectively to internal and external audits, and to share information across multiple locations.

SIMCO cuts through the layers of these challenges with its fully integrated suite of CERDAAC cloud solutions and services, which help quality and operations program managers drive operational excellence, minimize equipment downtime and prove compliance. In fact, many SIMCO customers implement

CERDAAC to address an urgent CAPA or quality challenge not addressed by their current system or software.

Managers can also use CERDAAC to identify out-of-tolerance (OOT) equipment and its location on the production floor. Using CERDAAC, SIMCO clients have gained, on average, a 287% ROI in business value.

Combining the capabilities of a traditional CMMS and an enterprise asset management (EAM) system, CERDAAC provides cloud solutions for managing the key assets and programs that surround production, including equipment calibration and maintenance, facilities management, workforce and partner compliance, and product use trace. Intuitive reports and dashboards help quality and operations professionals keep tabs on equipment service histories and proactively schedule services. CERDAAC also helps to determine whether the service can be performed at the client's own lab, one of SIMCO's nationwide network of 20+ labs, or if it needs to be sent to the original equipment manufacturer (OEM).

CERDAAC's cloud architecture makes it easy for clients to purchase, implement and maintain. Users access the software online through a subscription, with no on-premise hardware or software installation, and no maintenance required. Upgrades and updates are automatically applied and managed by SIMCO, minimizing any IT burden. Because every client's business processes are unique, SIMCO's CERDAAC software is also highly and easily configurable, using "clicks, not code." As a result, the deployment time for CERDAAC is typically around 2-3 months, with some clients implementing the software in as little as two weeks. SIMCO's CERDAAC experts also provide hands-on, in person training and support.

Another significant advantage for life sciences manufacturers using CERDAAC is that the software is prevalidated to meet the FDA's 21 CFR Part 11 and Part 820 regulatory standards. While many software providers offer extensive documentation that clients then use to validate their own systems, CERDAAC is prevalidated out of the box for its intended use, saving clients significant time, resources and expense.

SIMCO's unrivaled journey is a testament to the company's quest to extend the principles of Lean Six Sigma management from the production line to the equipment, people and programs supporting production. With decades of experience working with highly regulated manufacturers, SIMCO is the ideal partner for life sciences manufacturers being challenged to deliver lifesaving quality, leaner. [LS](#)



Sam Klooster,
VP of Software

SIMCO Electronics



*The annual listing of 10 companies that
are at the forefront of providing Life Science
Compliance solutions and transforming businesses*