

pharma

TECH OUTLOOK

**QUALITY
ASSURANCE
EDITION**

**SOFTWARE FOR REGULATED
OPERATIONS EXCELLENCE**

**SIMCO's
CERDAAC**

**Brian Kenna
CEO, SIMCO**



SIMCO's CERDAAC

SOFTWARE FOR REGULATED OPERATIONS EXCELLENCE

By Stacey Smith

What does a global life science company do to meet the highest standards of excellence when its current systems fall short?

This is what one global industry leader faced when software and process limitations kept taking down their production and R&D equipment. The company was using a combination of paper-based processes, spreadsheets, and a software system to manage calibration and preventive maintenance activities, causing an array of data entry and processes errors. In addition, more complex tasks such as Out-of-Tolerance (OOT) investigations were tracked using an entirely different paper-based process, causing paperwork to get lost during multiple handoffs, never making it to the archives.

They decided they needed a new system, one that allowed them to consolidate all their electronic forms

and workflows into one automated system. Compliance with FDA 21 CFR Part 11 was mandatory, including comprehensive documentation and audit trails. Finally, they wanted a system that would allow them to track events and trends over time.

The company turned to SIMCO's award-winning cloud software, CERDAAC. Among other benefits, CERDAAC led to a huge reduction in time spent maintaining data in multiple places. After a short deployment, they were able to save several hundred thousand dollars annually and generate a 477% ROI. This included cost savings on audits, validations, data entry, investigating Out-of-Tolerance events and more.

This is one of the many success stories that SIMCO, a leading provider of quality software and services to regulated manufacturers, has penned in recent years. The firm has helped some of the world's largest

Applying Digital Lean with:
A Pharmaceutical
and Medical Device
Technology Leader

- 477% ROI
- \$148,550 Savings Annually
- 1,000 Hours Saved in Audit Support



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CEO, SIMCO

manufacturers manage their calibration, maintenance, facilities, assets, audits, validations, and other manufacturing quality programs – improving compliance and reducing cost. “Through our innovative software and services, we are redefining quality, compliance, and profitability for highly regulated manufacturers, especially in the life sciences space,” says Brian Kenna, CEO of SIMCO.

Making Life-Saving Quality Leaner

“We’re seeing rapidly evolving, more complex quality and regulatory demands combined with a more challenging market that requires increased speed to market. Companies need to get products out the door faster and faster. Compliance teams are under constant pressure to do more with less, requiring a fundamental shift in leveraging technology to drive efficiencies and innovation. We’re partnering with our customers to apply lean concepts, digitize, coordinate and manage their workflows to ensure compliance and increase profits. We see this as an opportunity to enable them to free up funds to invest in their mission,” explains Kenna. “SIMCO helps customers increase quality and reduce costs – making life-saving quality leaner.”



Highly regulated manufacturers are required to support numerous internal and external audits – as many as 50 annually per facility. Dramatically reducing the audit burden is a main reason why 90% of regulated manufacturers are increasing their investment in digital transformation.

“This is where we take center stage. We have 60 years of experience working in high production, highly regulated environments, like manufacturing and R&D facilities. We know the space really well and can help them with their digital transformation,” asserts Kenna.



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Configurable, Connected, Intelligent

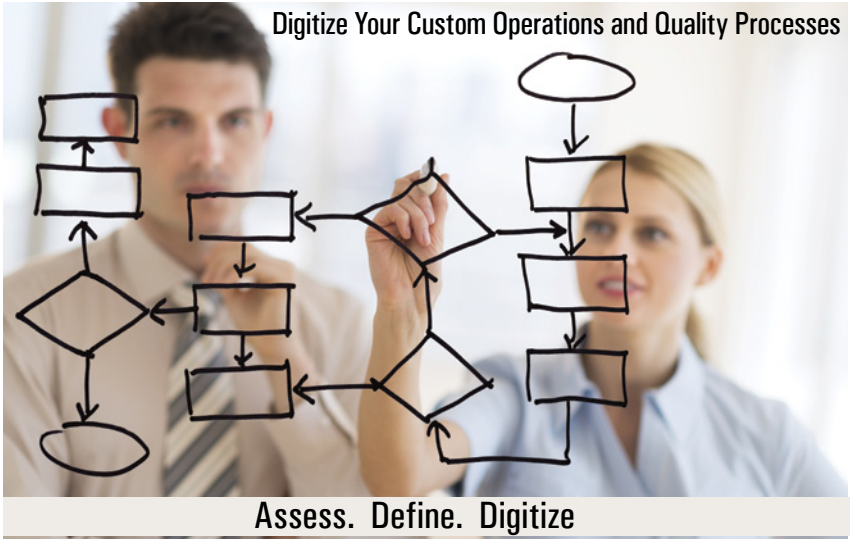
At the core of every SIMCO solution is CERDAAC – a purpose-built, regulated operations excellence platform designed specifically to extend lean six sigma practices to the processes surrounding the heavily-audited production line. What sets the platform apart is how quickly configurable and extensible it is. CERDAAC can digitize and streamline not only standard, but also one-of-a-kind forms and processes. It supports single programs – all the way up to a full suite of operations and quality needs – including calibration, maintenance, facilities, audits, validations, training, certifications, inspections, and more.



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With its native cloud architecture, CERDAAC offers zero IT overhead, making it easy to deploy across sites and geographies. It is pre-validated by SIMCO for FDA compliance and rapid

toolset that makes it easy to automate and streamline a wide variety of manufacturing support and quality processes.



deployment. “It integrates seamlessly into our customers’ internal systems, enabling users to have control of their program but also feed information into the right systems, like ERP and quality management systems. We have also invested a lot in the security and privacy compliance for Europe and the U.S., and the growing needs around GDPR,” informs Kenna.

There is a lot of intelligence built into the CERDAAC platform, which can aggregate and leverage service data to help manufacturers make better decisions across their programs. “For example, if someone is using a tool, we help track the tool’s failure rate and total cost of ownership across all our service customers. With this insight, customers can make informed purchase decisions that minimize failure rates and total cost of ownership,” adds Kenna. In short, via the CERDAAC platform, SIMCO offers manufacturing and quality organizations a flexible, configurable



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Six Decades of Service Experience

Unlike pure-play software or service providers, SIMCO is unique in offering both. In addition to its CERDAAC software, SIMCO is the industry leader in providing calibration and repair services to manufacturers of life-saving products. The firm serves 3,000 customers, including 16 of the top 20 global biomedical device manufacturers and 14 of the top 20 global aerospace and defense contractors. Founded in 1962 to service

NASA and high technology firms in Silicon Valley, SIMCO is committed to providing the highest level of quality and customer service in the industry.

CERDAAC was forged out of six decades of service experience and 15 million services completed. “That’s our competitive advantage – we’re not just Silicon Valley techies, we’re quality & operations veterans who have created a platform that is truly optimized for professionals like ourselves. Our own services team is our most demanding customer,” states Kenna. “And to see our customers embrace the software and use it to automate so many different processes is the ultimate reward.”

The world has changed immensely in the last 18 months, and so has the way companies do business and deliver their products and services to customers. Businesses that once mapped digital strategy in one- to

three-year phases have had to scale their initiatives in a matter of days or weeks. “Against this backdrop, we are solving new problems for customers every day – like enabling them to onboard and enroll life-saving assets into their systems remotely or tracking COVID testing and vaccination status of employees and vendors. Having a rapidly configurable, cloud-based system like CERDAAC has enabled our customers to quickly adapt to ever-changing business requirements,” wraps up Kenna.