

Case Study: Medical Technology

Global leader in medical technology chooses CERDAAC to digitize calibration and maintenance processes and save \$3M annually



Overview

A global leader in medical technology recently undertook an important company-wide initiative to digitize processes to drive cost savings and improve process efficiencies.

The Senior Manager of Facilities Engineering needed a new system to digitize the company's test equipment calibration and preventive maintenance processes across the company's multiple global sites. After evaluating the different alternatives on the market, his team chose CERDAAC to meet the challenge.



5 Year ROI Results:

\$3Million

in cost savings

100K+ Hours

of time saved

60K+ Assets

managed by CERDAAC

80K+ Services

managed by CERDAAC



That's people time. That's man hours. That's cost. If you can reduce those hours, and be more efficient, that's where a lot of the saving more efficient, that's where a lot of the savings are generated. Those are real dollars."



The Challenge:

A Hodgepodge of Systems and Processes

As the company grew in the past, each of the different manufacturing sites developed different systems and processes to manage equipment calibration, preventive maintenance, and repair. Some were using different calibration and maintenance management software applications, some were using spreadsheets, and some simply relied on paper documentation to track which equipment needed calibration or maintenance, when it was serviced, and whether it was found to be in or out of tolerance.

"There was a real hodgepodge and all the sites had different ways of managing calibration and preventive maintenance. We wanted to consolidate, compare all of them, pick the best one, and go with it." says the manager.

The company faced numerous challenges that limited its ability to efficiently manage its calibration and preventive maintenance processes, including:

- Multiple siloed systems: Each site had its own systems, making it difficult to integrate and manage applications across sites.
- **Inconsistent processes:** Each site had its own processes, making it difficult to report and manage across sites.
- **Insufficient reporting:** Executives needed access to high-level information about calibration and PM processes.
- **Limited audit support:** It was difficult to locate and provide the necessary documentation for quality audits.
- No visibility across sites: The variety of systems and processes made it impossible to have a global view of key quality metrics.
- Unnecessary IT burden: Each department and site was responsible for purchasing and maintaining its own IT systems.
- **Expensive to maintain:** The system required a high number of people hours to track and service equipment, and to respond to audits.



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We selected CERDAAC to manage both our calibration and preventive maintenance services across all of our sites. The nice thing is that CERDAAC works both for calibration and for preventive maintenance, because in a lot of departments those processes are combined. CERDAAC's combination of capabilities and cost savings made the business case for us," the manager confirms.

Requirements

The manager was tasked with finding and implementing a system that would automate, streamline, and reduce the costs of the current approach by digitizing and standardizing information, systems, and processes across multiple global manufacturing sites. Key goals for the new solution included:

Improved quality and regulatory compliance

- Ability to enforce consistent process execution across all sites
- Ensure audit success with a robust, validated system

Streamlined operations

- Eliminate the efforts spent installing, validating, and maintaining multiple systems
- Drive operational efficiency with a highly automated system

Global visibility

- · Provide executive level dashboards for tracking high level metrics at a glance
- · Ability to quickly drill down into details on any asset or service

Evaluation Process

The company first looked at its existing systems to see if it could find a good internal solution already in use. In addition to the existing variety of calibration and preventive maintenance systems and processes, the company was already using SAP's enterprise software for its controls, so the company first looked to see if it could use that application to manage calibration and repair as well. "We found that SAP was okay for preventive maintenance, but they were not strong in calibration," says the manager.

After a rigorous evaluation, one solution stood out.



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The Solution: CERDAAC

SIMCO presented the business case for its CERDAAC solution to demonstrate that, beyond simply digitizing processes, the software provided real cost savings and efficiencies that would have a significant impact on the company's bottom line.

For example, the organization has over 60,000 assets across over a dozen different manufacturing sites. Each of these assets needs monthly or quarterly calibration and preventive maintenance.



"That's people time. That's man hours. That's cost. If you can reduce those hours, and be more efficient, that's where a lot of the savings are generated. Those are real dollars," explains the manager.

SIMCO originally estimated that CERDAAC would help the company achieve \$225,000 in annualized cost savings. Since then, the number of assets being managed by CERDAAC have dramatically increased and so have both the time and cost savings.

"We're saving maybe 10–12 minutes per service. When you start adding that up and you get in the 10,000, 20,000, 50,000 number of services range, that's significant money," according to the manager.

In fact, in a recent analysis performed with the company, SIMCO found the efficiency gains have added up to over 100,000 hours of time saved, and over \$3 million USD in cost savings over five years.

Original Annualized Savings

\$225K

\$50K System validation savings

\$50K IT savings

\$45K Hardware & software savings

\$30K Reduced non-conformance costs

\$25K Streamlined operations savings

\$20K Reduced CapEx spending

\$5K Reduced training costs

Annualized Savings Five Years Later

\$3M

plus...

100K+ Hours of time saved

60K+ Assets managed by CERDAAC

80K+ Services managed by CERDAAC

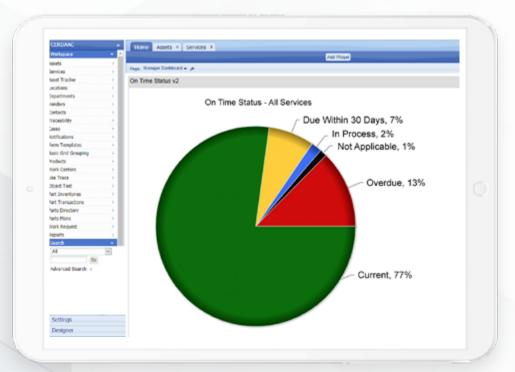




Acing Audits

As a highly regulated and specialized manufacturing environment, the company's facilities and equipment are subject to frequent internal and external audits. Test equipment must be certified at regular intervals to prove it is operating within specific tolerance ranges, and calibration and preventive maintenance must be scheduled regularly and clearly documented. By capturing each location's assets in a database and automating those processes, the company has been able to greatly improve the accuracy and efficiency of those processes while significantly reducing costs.

"We've had real success with our audits. When an auditor visits one of our locations, we bring them right into the lab and we use CERDAAC to answer their questions right there on the spot. With CERDAAC, we cannot only pull up the asset and the service, we can also pull up all the certifications and the history for each one. It's all there electronically. There is no need to dig through files and paper," says the manager.



A Pre-Validated System

One of the key benefits of the CERDAAC system for the company was the fact that CERDAAC is pre-validated.

"We use a large real estate company who has their own system, but it's not validated. So I'm pulling everything out of their system and putting it into CERDAAC. In a regulated environment, you have to have a validated database and that was a big part of why we chose CERDAAC."

SIMCO Validation includes:

- Validated to 21 CFR Parts 11 and 820
- Re-validated when software is updated
- Independently audited and accepted by over 600 life sciences companies

Business Visibility

With the new system, quality professionals get access to the detailed information they need to manage equipment calibration and preventive maintenance. In addition, the system provides executives with dashboards that summarize the important trends and information they want to see.





The Business Case for CERDAAC

CERDAAC checked all the boxes the company had in mind for the new system, along with some extra benefits.

Those combined included:

- A master database where all assets could be stored, services scheduled and tracked
- ✓ User friendly system that could be quicky implemented and deliver immediate ROI
- ✓ Business-level dashboards for executive management
- Optimized for "lives at stake" healthcare market with over 600 healthcare customers
- Pre-validated: CERDAAC was the only software provider to offer a prevalidated system
- ☑ Cloud-based application that eliminates any IT management or expense burden
- Flexible and easily tailored and customized to specific business requirements
- ✓ Integrates with company's existing SAP manufacturing system inexperienced users.
- ☑ Easy access and visibility of asset-related documents.



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Every department is graded through the quality department. With CERDAAC, our directors can take one glance ... and know exactly where they stand"

"The directors don't need or want to see all of the information about thousands of assets," the manager explains. "They want to know our goal and whether we met it with a clear, quick glance. CERDAAC gives them the dashboards they need to manage the business."

The site directors measure their facilities' performance through the lens of quality.

"Every department is graded through the quality department. With CERDAAC, our directors can take one glance and see if they're trending right, or if they're above the line or below the line. In one glance they know exactly where they stand," says the manager.

Cloud-Based System Eliminates IT Burden

One of the key benefits of CERDAAC was adopting a cloud-based system.

"With CERDAAC, there are no servers to install or manage. When you're a big corporation like us, IT doesn't like anyone outside the company storing their servers on site and being part of our network. By being a cloud system, CERDAAC gives us the security of knowing it's not on our physical network."

In addition, the lack of an on-premise system saves the manager a significant amount of effort.

"Everything that is server related or IT related that I'm involved in, and has my name on it, I have to manage. Now, if anyone asks about the security of our system, CERDAAC has all the documentation to prove that we are taking the right measures." the manager explains.



Driving Innovation

With CERDAAC system in place, the company obtains process and operational efficiencies that help the business run faster and leaner. And the benefits go even further: CERDAAC is proud to be helping the company in its mission to drive the advancement of new innovations in health care.

"The more we can show that our equipment is in tolerance, or pull it into tighter specs, the more chance we have of making a new discovery or making an improvement. If I can add more precision, more accuracy, give them an extra decimal point, that might be the difference between making a discovery or not. Once I was able to prove that through better standards and better calibration, they might be able to find that thing they're looking for, that's when things turn around. So I'm always trying to drive toward that goal," explains the manager.

C CERDAAC by SIMCO

CERDAAC is a leading computerized maintenance management system that delivers operations excellence and automates and coordinates calibration, maintenance, validations, and more to ensure compliance with efficiency and no downtime.

CERDAAC is purpose-built for highly regulated manufacturers who need to deliver high quality products and profits while meeting complex regulatory requirements.

Trusted by over 3,000 companies worldwide including Abbott, Corning, Siemens, Varian, and Stryker and many more. Learn more at www.cerdaac.com

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