



BUSINESS CASE

As part of the evaluation process, SIMCO provided WuXi AppTec with a business case detailing the savings SIMCO's CERDAAC software would provide over the company's current approach, with cost savings and other benefits including:

477% Return on Investment

\$148,550 savings annually including:

~1000 hours saved in audit support

Cost Savings: 138,550/year

- \$33,750 in Audit Costs Time Savings
- \$32,500 in Data Entry Cost Savings
- \$30,000 in Equipment Downtime Cost Avoidance
- \$18,000 in SaaS Validation Costs Savings
- \$10,800 due to OOT Event Traceability
- \$9,000 OOT Case Management Time Savings
- \$4,500 reduction in inefficiencies due to limited license cost savings

Additional Benefits >\$10,000/year:

- Reduction in Human Error
- Time Savings via Automatic Reports
- Increased Data Analytics
- Automatic Backups
- Paper Cert is Missing or Destroyed
- Correct Procedures/Specifications
- Ensure Audit Readiness
- Reduced IT Costs due to Cloud-based Solution

WuXi AppTec

Pharmaceutical and medical device technology leader uses SIMCO CERDAAC to meet high industry and regulatory standards of excellence

Overview

WuXi AppTec is a leading global pharmaceutical and medical device open-access technology company with operations in 30 countries worldwide. Founded as a single laboratory, WuXi today has 27 locations and over 1,800 employees. The company's mission is to build an open-access platform with the most comprehensive capabilities and technologies in the global healthcare industry, with the goal that "every drug can be made and every disease can be treated."

Adherence to best practices in service delivery has allowed WuXi to demonstrate outstanding achievement in leadership, technological innovation as well as customer service, and receive recognition from organizations worldwide over the years. As part of this dedication to industry excellence, the company must keep its pharmaceutical and medical device tools and equipment in top condition and precisely calibrated. To help achieve those standards of excellence, WuXi AppTec uses SIMCO's CERDAAC software.

The Challenge:

Prior to implementing SIMCO CERDAAC, WuXi AppTec was using a combination of manual, paper-based processes, spreadsheets and a software system from Blue Mountain to schedule its calibration and preventive maintenance services. While basic scheduling tasks were performed using the software, raw data such as calibration certificates were kept elsewhere, and a separate large spreadsheet contained the master asset list. In addition, more complex tasks, such as out of tolerance investigations, were tracked using an entirely different paper-based system. The result was a lot of redundant data entry and processes that were prone to error.

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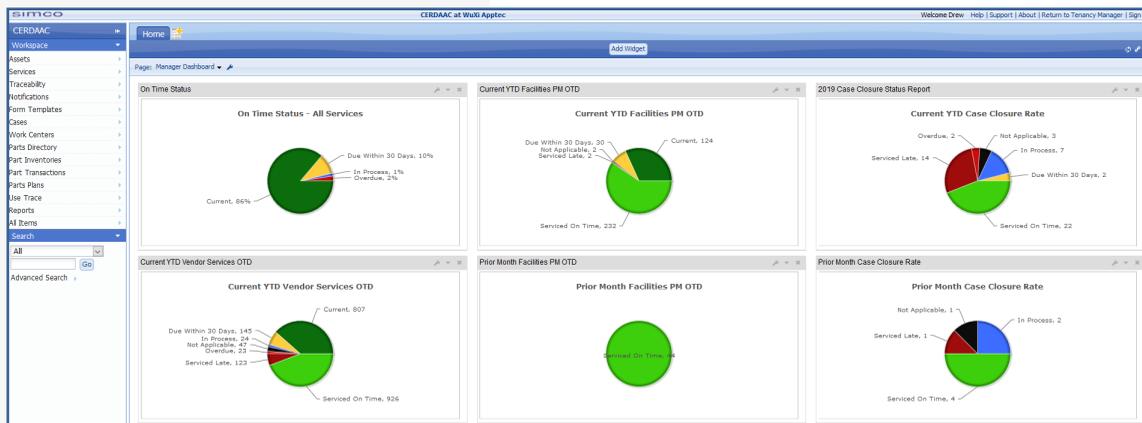
“With the old system it was pretty straightforward to enter data in, but we were having issues with paperwork getting lost because of multiple handoffs or a document never making it to the archives,” says Lukin Moline, Validation Specialist at WuXi AppTec’s Lab Testing Division. “If it’s not documented in our industry, it didn’t happen, and that put us at risk in many ways.”

The company recognized it needed a new system to better address its needs. “We have a requirement from our regulators to maintain a master asset list,” explains Moline. “The old software really wasn’t able to do that for us in a user friendly way.” In addition, better reporting was a top requirement. “The reporting of KPIs and other metrics out of our previous system was practically impossible. It was like driving down the highway without being able to see how fast you’re going, or if your check engine light is on.”

CERDAAC Meets Key WuXi Requirements

WuXi AppTec evaluated several different potential solutions to take the place of its combination of outdated software and manual processes. One requirement was a solution that supported Title 21 CFR Part 11 compliance, with comprehensive documentation and audit support.

The company also needed a solution that would allow it to move away from paper based systems and processes to more electronic forms, documentation and approval. Finally, WuXi wanted a system that would allow the company to more readily track events and trends over



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time. According to Moline, many of the systems WuXi AppTec evaluated came with a very large price tag and limited user licenses. “With the old system, equipment owners were reliant on my staff to look up information, because there were not enough licenses available to provide everyone with view access to the database,” he explains.

WuXi chose SIMCO software based on its combination of features, ease of use, reporting and unlimited user licensing model. Because SIMCO is a cloud-based application, users can simply log in using a web browser. And because SIMCO’s pricing is based on the number of assets being managed and not the number of users, Moline can provide access to anyone who needs it. “With CERDAAC, I can now give all 270 of our employees at our St. Paul site various user level access to the system at no additional cost,” says Moline.

While some software systems the company evaluated offered broad functionality, WuXi found SIMCO CERDAAC was better targeted to its needs and more cost-effective. “If we had purchased ten licenses of one of the other systems, it would have taken us a decade to spend that same amount of money with CERDAAC,

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Built-In Functionality and Flexibility

Today, WuXi uses SIMCO CERDAAC to manage calibration and repair services for over 2,000 assets including equipment, instruments and commissioned laboratory spaces. The company also uses it to maintain schedules of services for those assets, including preventive maintenance, calibration, certifications and other annual qualifications, and periodic reviews. Raw data including calibration certificates, work orders and even vendor contact information are all stored in CERDAAC,

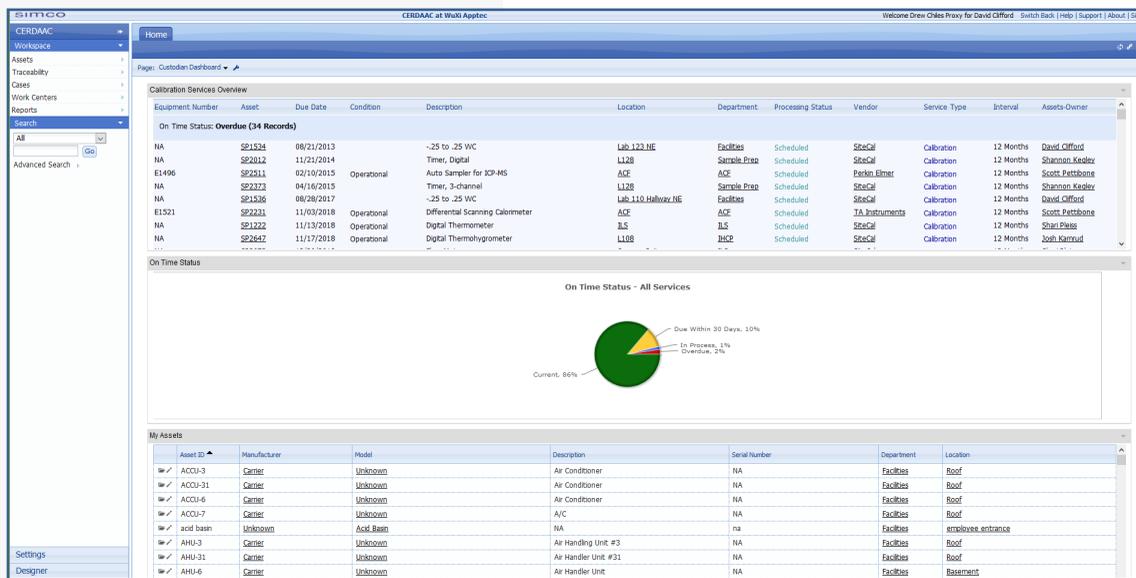
eliminating the need for redundant spreadsheets and paper processes. “There is a huge reduction in the amount of time we spend because we no longer have to maintain multiple databases,” says Moline. “We definitely are making much more efficient use of resources with CERDAAC.”

WuXi also uses the CERDAAC Cases module for out of tolerance report investigations, and for reports and KPI monitoring. “For

this year to date we have 45% of our cases closed within their due date – which is much higher than it used to be,” says Moline. “It used to be around 10%. That’s a huge step in the right direction, and I think as more people get used to completing that electronic workflow, we’re going to see that number continue to improve. We are trending in the right direction, and I can tell that at a glance just by looking at my CERDAAC dashboard.”

Using CERDAAC, Moline is able to easily configure options in SIMCO for specific services and events. “Some of the functionality we were looking for was kind of clunky in those other systems,” says Moline. “We would have had to find workarounds for some of the capabilities we needed. CERDAAC really allowed us to customize or configure the options we needed very easily. It’s very intuitive, as well as very easy to learn and use.”

Moline likes that he is also able to easily add custom fields for things that he wants to see on a regular basis. For example: if an incubator has a specific range of use and it is mapped at a specific set point, he is able to add that information to the equipment information screen. “Those data fields are very easy to add, and they provide us with ready access to the information we need to see for that asset,” he explains.



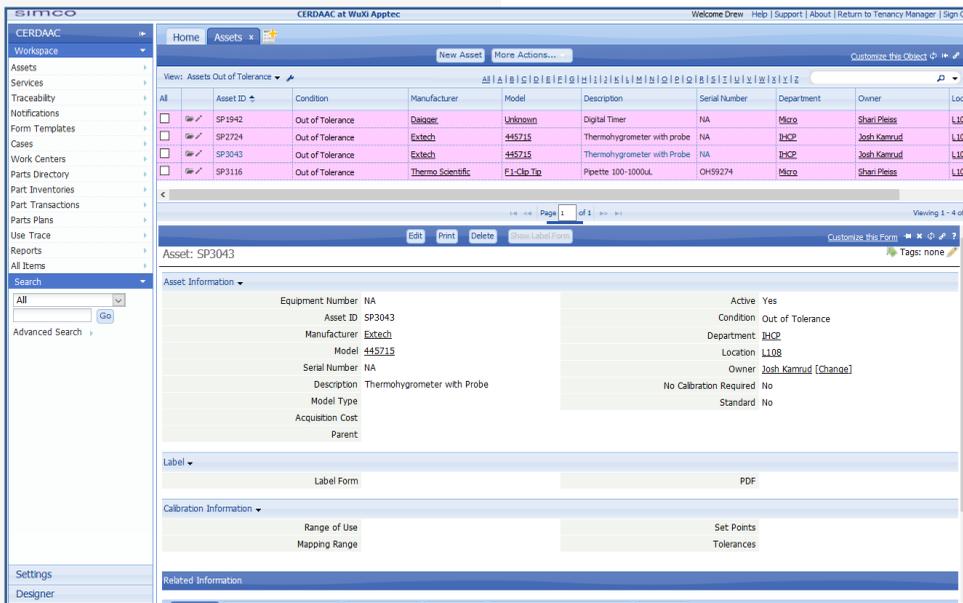
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Clear Visibility for All

Customizable dashboard widgets allow Moline to build reports and dashboards, giving him important data at a glance. “Being able to graph data on the homepage in order to just see the state of the program at a glance is by far one of my favorite things,” he says. “And the ability to customize that based off of the user role is very nice as well. I see things that only a system admin would see, but others, like laboratory managers, only see what is relevant to them and their departments.”

Using CERDAAC, Moline generates automatic reports to end users and to various other stakeholders. “I have a report set up to go out to my facilities team every week on Monday morning of all the preventative maintenance activities that they are responsible to complete before the end of the month. Knowing that report is always current really helps make sure that they’re not missing something by accident.”



Acing Audits

WuXi has on average 60 to 80 client audits a year, as well as audits from many different U.S. and international regulators. The audits cover many different aspects of the medical industry, including testing of the company’s medical devices, pharmaceuticals and biologics, and contract manufacturing and tissue based products. “With CERDAAC, WuXi now has the documentation it needs to provide regulators and clients. We’ve mitigated our regulatory risk by utilizing CERDAAC software and making that workflow an electronic one,” says Moline.

The company’s quality systems group typically hosts these client and regulatory audits. Previously, the individual hosting the audit would email the archivist to request the records in question from the company’s archives. The archivist would then go and find the relevant records, then have someone review them before they were brought in front of the clients to be presented. The entire process could take anywhere from 30 minutes to several hours. “With CERDAAC, they’re able to pull up electronically the data and certificates for our clients as they are requesting it, right there on the spot,” says Moline. “It takes just seconds, so CERDAAC is saving us a lot of time and resources.

In addition to time saved, the ability to provide instant documentation reinforces the company’s reputation for excellence. “The fact that we can provide accurate documentation that quickly sends a message to the auditor that we have a process and a system that is in control,” says Moline. “It helps you answer those questions instantly, and we’re able to say yes, we have that data, just tell us what you want to see and we can show it to you.”



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