CASE STUDY

PHARMA

Pharmaceutical leader with large network of PET radiopharmacies uses SIMCO CERDAAC to transform its operations in compliance with new FDA regulations.

SUMMARY

- 400 users
- 43 sites
- 5,000 assets tracked
- Staff training and certifications also tracked in CERDAAC

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Overview

What does a pharmaceutical company with millions of dollars invested in processes, people and equipment do when the entire industry's compliance requirements suddenly change?

That is the challenge one pharmaceutical company faced when its industry transitioned from oversight under the rules governing compounding pharmaceuticals to FDA regulatory compliance. The company, which owns and operates a large, global network of PET radiopharmacies, turned to SIMCO's CERDAAC software for the solution.

Today, more than 400 employees across 43 sites in the US use SIMCO's CERDAAC software to track the compliance of over 5,000 assets, as well as staff training and certification requirements. "From a regulatory standpoint, it's one of the key tools we use to show that we're in compliance with the FDA's requirements," says the company's spokesperson.

The Challenge: New FDA Oversight Changes Compliance Requirements

PET stands for "positron-emission tomography," a nuclear medicine functional imaging technique that is used to observe metabolic processes in the body as an aid to the diagnosis of disease. The company developed the technique of using a radioactive isotope which, when combined with a certain biomarker, could be injected into a human with the goal of tracking the progression of disease in PET scans. Today, the company operates a large network of PET radiopharmacies with over 43 locations worldwide.

Initially, the company's tracers were considered by the industry to be a "compounded pharmaceutical"—a pharmaceutical preparation created by a licensed pharmacist to meet the unique needs of an individual patient when a commercially available drug does not meet those needs. As such, the company's tracers were regulated by the board of compounding pharmacies in each state.

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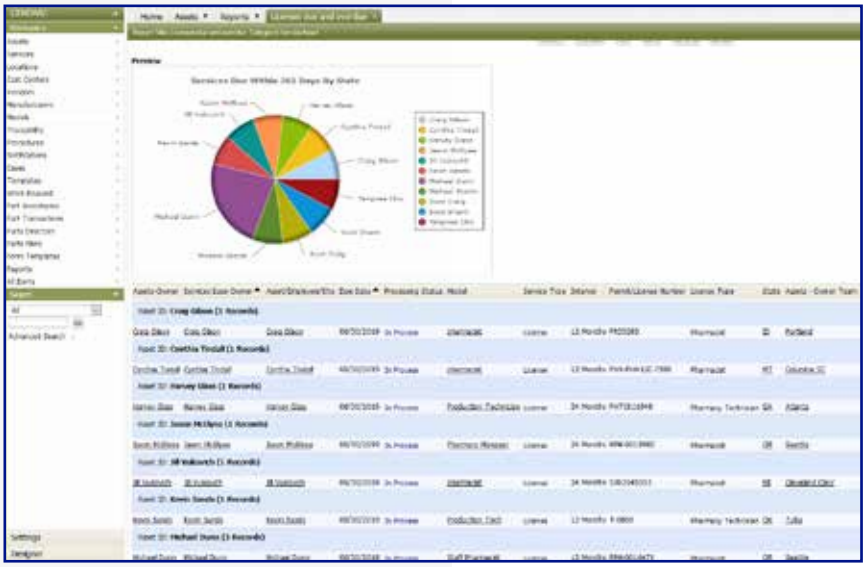
In 2009, the US Food & Drug Administration announced its intention to take over the regulation of PET tracers. By 2012, the FDA had published CGMP 212, the new regulatory requirement for PET manufacturing. Suddenly, the company was faced with the need to undergo a complete transformation of its manufacturing process controls and reporting requirements in order to meet the compliance requirements of the new standard.

"When the FDA got involved, the industry had to mature quite quickly," says the spokesperson. "With the change in regulatory requirements, we realized we did not have the right controls in place for tracking the calibration and the maintenance of equipment used in the manufacturing process to meet these new requirements."



A team at the company considered the options. The company was using an Oracle ERP system at the time, but the system did not include the manufacturing capabilities it needed. The unique nature of radiopharmaceutical manufacturing, combined with the company's large network of sites throughout the US, made it difficult to find an off the shelf solution that would meet the company's needs.

"Most of the systems we evaluated were either geared toward a single manufacturing plant, or they had been designed for the simpler compliance requirements of a compounding pharmacy," says the company's spokesperson. "We couldn't find anything that was both sophisticated enough and flexible enough to meet our needs."

The Solution: SIMCO CERDAAC®

The team decided to look within its own organization for a solution, and discovered that certain parts of the company, including the laboratory diagnostics area, was using SIMCO's CERDAAC® software. SIMCO CERDAAC is an advanced, cloud-based software service that integrates calibration, maintenance and other service management for assets serviced by SIMCO, internal departments or other service vendors.

"After our initial evaluation of CERDAAC, we realized it was the only solution we had found on the market that would help us meet our needs and the new, more stringent FDA requirements."

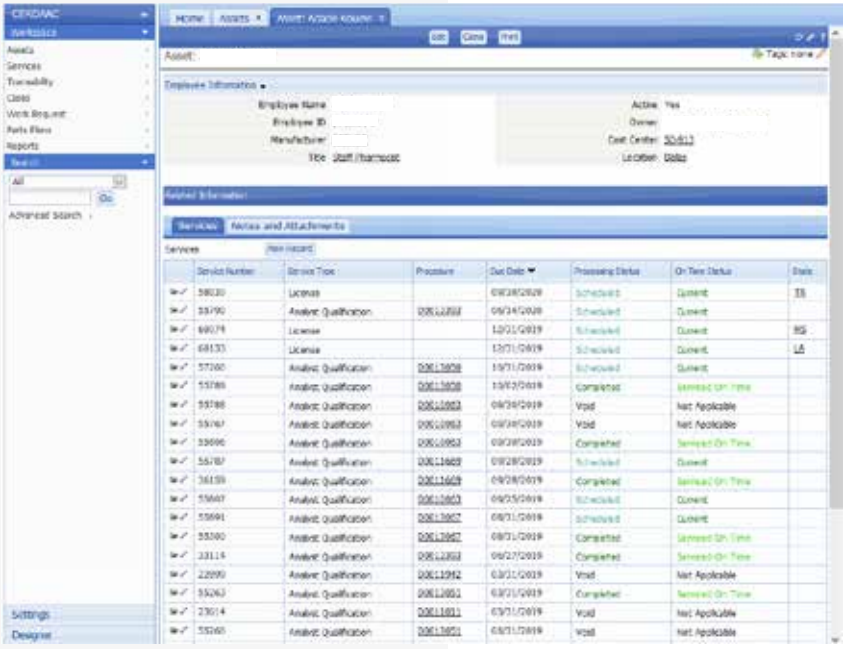
A proven solution that helps thousands of organizations increase efficiency, improve compliance, and reduce costs, CERDAAC provides advanced asset and service workflow management, as well as visibility into service status, program spending, quality compliance, key performance metrics and more. "After our initial evaluation of CERDAAC, we realized it was the only solution we had found on the market that would help us meet our needs and the new, more stringent FDA requirements."

"We now have the primary aspects of our business, with all of our licenses and permits, fully implemented in CERDAAC. Our most critical qualifications are fully implemented, and our cyclotron and chemistry systems are all completely tracked in SIMCO CERDAAC."

Tracking Both Equipment and Human Assets

In less than a year, the company was able to implement CERDAAC across all of its 43 pharmaceutical manufacturing sites. Today, it uses CERDAAC to track several different processes, including calibration, preventive maintenance, case management, use trace, software validation and employee certifications. As a cloud-based service, there was no on-premise software or additional computer equipment needed to implement CERDAAC. The company simply needed to adapt the software to its unique requirements.

The company's implementation is focused on thirteen key qualifications and services that are the company's top priority, and are tracked across all the sites in terms of utilization. "Our biggest challenge was not the software, it was the culture shift in our business," explains the spokesperson. "Traditionally, our business was run by pharmacists, meaning each of our site managers is typically a pharmacist. Our typical site staff did not have the strong background in metrology needed to use the software effectively and meet these new FDA compliance requirements."



The company's implementation of CERDAAC posed another unique challenge. In addition to tracking assets, such as calibration equipment, the company wanted to use the software for a new purpose: to track the licenses, permits and qualifications of its staff, as well as the pharmacists' licenses for each site. Because it produces radioactive material, reviewing and renewing those licenses and qualifications in a timely manner is key to helping the company stay in compliance with the FDA's regulation.

"We now have the primary aspects of our business, with all of our licenses and permits, fully implemented in CERDAAC," says the spokesperson. "Our most critical qualifications are fully implemented, and our cyclotron and chemistry systems are all completely tracked in SIMCO CERDAAC."

"With CERDAAC, we are able to prove full compliance with all of our regulatory requirements, including our staff's licenses and permits as well as our equipment."

Results: Full Compliance with FDA Regulations

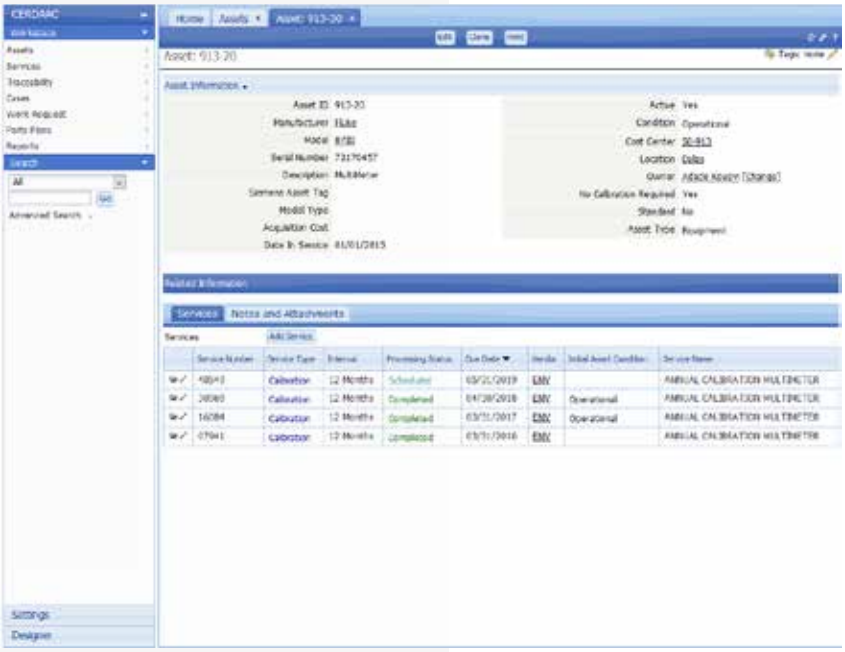
The implementation, including the new twist on tracking staff licenses and qualifications, has been a success. "With CERDAAC, we are able to prove full compliance with all of our regulatory requirements, including our staff's licenses and permits as well as our equipment" says the spokesperson. "We have a process now so when new equipment is added, it's part of our quality change control process in CERDAAC. We generate CERDAAC reports on a regular basis to find out whose qualifications are coming up for renewal, so we don't miss an important date. We can also tell what equipment is out of qualification and where the equipment is located so it can be updated or replaced."

"With CERDAAC, we've accomplished a complete transformation of our compliance tracking and reporting processes, and we will continue to use it to improve the quality and efficiency of those operations."

The spokesperson acknowledges that, without CERDAAC, it would be impossible to meet the FDA's requirements for documentation of the company's equipment and human compliance. Every site is its own unique site in terms of compliance, and the FDA typically audits each site every two years.

"Last year we had thirty-four FDA audits," says the spokesperson. With CERDAAC, we are able to produce what we need to prove our compliance both from a staff qualification standpoint as well as an equipment standpoint."

In the future, the company plans to expand its use of SIMCO CERDAAC, utilizing the software across all of its equipment and services equally at all of its sites. The company may also decide to take advantage of CERDAAC's parts utilization tracking features, as well as some of the planning aspects of parts, including replacement planning.



The final test of any software implementation is a yes or no question: would you recommend it to a colleague? According to the company's spokesperson, "We absolutely would and do recommend SIMCO CERDAAC to other pharmaceutical manufacturers. With CERDAAC, we've accomplished a complete transformation of our compliance tracking and reporting processes, and we will continue to use it to improve the quality and efficiency of those operations."

"Last year we had 34 FDA audits. With CERDAAC, we are able to produce what we need to prove our compliance both from a staff qualification standpoint as well as an equipment standpoint."

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