

Case Study: ViewRay

Medical device leader uses CERDAAC to enroll, track, calibrate and manage lifesaving equipment

Overview

ViewRay Uses CERDAAC Calibration Cloud, Maintenance Cloud, and Enroll and Control Cloud

303%

CERDAAC provides ViewRay 303%
Return on Investment

80%

CERDAAC Generates 80% Time Savings
Over Previous Manual Processes

The ViewRay Challenge

ViewRay, Inc. (Nasdaq: VRAY), designs, manufactures, and markets the MRIdian® MRI-Guided Radiation Therapy System. MRIdian is built upon a proprietary high-definition MR imaging system designed from the ground up to address the unique challenges and clinical workflow for advanced radiation oncology. Unlike MR systems used in diagnostic radiology, MRIdian's high-definition MR was purpose-built to address specific challenges, including beam

distortion, skin toxicity, and other concerns that potentially may arise when high magnetic fields interact with radiation beams.

ViewRay has over 1,000 manufacturing related tools used in multiple locations around the globe which must be precisely calibrated, tracked and maintained. As a medical device company, ViewRay is regulated by the FDA and subject to audits and inspections. The company uses CERDAAC software to streamline its asset management processes.

Sidqdeep Ghoman is a Materials Planner at ViewRay whose focus is on making sure the company's tools are calibrated, tracked and maintained according to both the company's and the FDA requirements. When Ghoman joined ViewRay, the company's processes for calibrating and maintaining its tools, and tracking their locations, was a mix of manual paper processes, PDFs and spreadsheets. While ViewRay already had CERDAAC installed, the company was mainly using it as a database to store a list of its tools, and not leveraging its full capabilities.

As an example, the ViewRay team members were still creating PDFs of forms manually to track assets. Sidqdeep would fill out the information on the form, and then email it to the company's calibration and maintenance engineers for review. The engineer would review the form, sign it, and then email the PDF back to Sidqdeep. Next, the form would be sent to the Quality department for signature, and so on – a process that could take days or even weeks. "If there was an issue, I had to go back and edit the form, review it, create another copy, and then email those copies to everyone all over again," explains Sidqdeep.

CERDAAC Saves 80% of Time Previously Spent Chasing Paper

Today, between 20-30 employees at ViewRay use a combination of CERDAAC's Calibration Cloud, Enroll and Control Cloud, and Maintenance Cloud to efficiently manage over 1,000 tools and other assets. Users range from the materials team to quality and engineering departments to management, which uses CERDAAC to view reports on tool availability.

With CERDAAC, the ViewRay materials team now has all the data it needs in one single source of record. Users can access the system and instantly see the location and status of their tools, including tool availability, location, and service

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— Sidqdeep Ghoman

status. “It’s easier to have everything, including digital signatures, in CERDAAC,” says Sidqdeep. “I no longer have to create PDFs and send them to multiple people each time. CERDAAC sends notifications to the right people automatically, and each of the different

stakeholders can sign and approve the forms at their convenience. Everything is tracked in one system, so we are ready whenever there’s an audit.”

Using CERDAAC, if someone in the Quality department finds an error in a form, he or she can simply log into CERDAAC and reject the request, and the software automatically sends a notification back to the engineers to review it again.

“There’s less work, fewer emails, and less chaos in the process,” says Sidqdeep. “I can instantly see which signatures are missing and then automatically notify those users again.”

CERDAAC automatically pre-populates ViewRay’s asset data, manages and triggers notifications when an asset needs approval from the next person in the chain, and records a complete audit trail of all changes. “CERDAAC has saved 80% of the time that I used to spend creating forms, gathering signatures and trying to figure out what’s happening with our tools,” says Sidqdeep. “Now, I can just go into CERDAAC and see the status of tools instantly. I can find out everything that I need to know. Using CERDAAC’s automated notifications, I can see at a glance the tasks that need to be done in the next 30 or 60 days.”

Enrolling and Deactivating Assets Just Got Easier

ViewRay recently added CERDAAC Enroll and Control Cloud to its implementation. The company enrolls and deactivates an average of 30 tools per month, a job that CERDAAC makes faster and more efficient. Before, ViewRay’s process required users to manually fill out Microsoft Word documents to enroll, change and deactivate assets. The documents then had to be emailed back and forth between engineering and Quality to approve.

"Before, there were a lot of gaps in our process," says Sidqdeep. "We were using a hard drive to store all of our asset forms. When we needed to see a form, it took forever to load just to see the status of one asset, and we didn't even know which assets were missing what type of form. We had a lot of tools in service that were missing forms which is a compliance risk. But with the help of CERDAAC, we are avoiding that. CERDAAC shows us when the asset is not active and we still have to work on completing the forms. We can't put that asset in service until all the documentation is complete."



to put in the serial numbers and maybe

As an FDA regulated manufacturer, ViewRay is subject to external

a CAPA (Corrective and Preventive Action). The CAPA is an approach used by the FDA to investigate and resolve quality issues along with identifying their causes.

When Sidqdeep first joined ViewRay, the company had six different CAPAs related to tools that were missing forms and other data. She estimates it took four months to resolve those CAPAs, with countless hours spent reaching out to every manufacturing site to determine the location and status of the tools in question.

“With CERDAAC Enroll and Control, we were able to fill those gaps we had in our asset records and processes,” says Sidqdeep. As a result, during the company’s most recent audit, we had zero CAPAs related to tools. That is amazing!”

CERDAAC has made the entire process of responding to FDA audits easier.

“Whenever an auditor sees a tool on site, they can see that it’s labeled correctly and we are using it correctly, says Sidqdeep. And when they ask questions, I can just log into CERDAAC and search for the tools or assets they want to see, and pull up the report within seconds.”



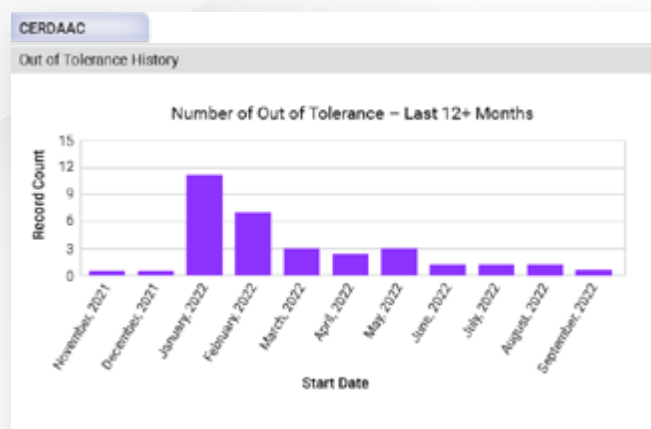
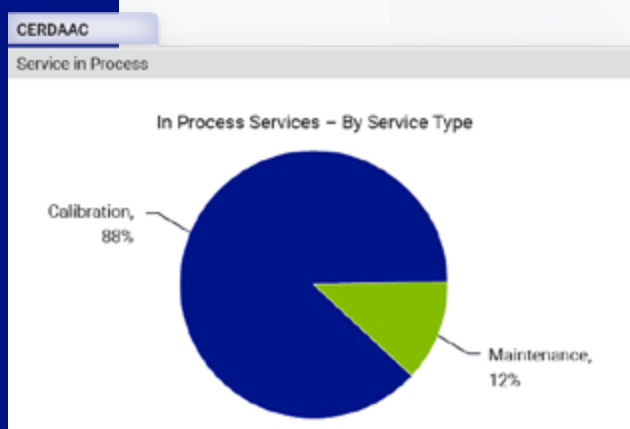
No More Expensive Equipment Delays

Making sure tools and other assets are calibrated, maintained and available for use is key to minimizing ViewRay's production downtime. In fact, Sidqdeep estimates that delays in equipment availability were resulting in installation delays that cost the company \$1,000/day. Before using CERDAAC for asset calibration and maintenance management, those delays happened on average once per month.

Using CERDAAC, ViewRay was able to eliminate most equipment delays, resulting in an annual savings of \$12,000.

"Our equipment approvals no longer fall through the cracks, so there are no more delays in getting those tools into the field," says Sidqdeep. With CERDAAC, I know the exact location of every tool. When a team requests a tool, I can tell them whether we have it available near their site and ship it without delay."

Ensuring those tools are precisely calibrated is another key to making sure they are able to be utilized. "Before implementing CERDAAC, our On Time Calibration metric was around 50%," says Sidqdeep. "With CERDAAC, it's closer to 96%. That's how much CERDAAC has helped us improve our on-time calibration metrics."



CERDAAC's Ease of Use Saves

Before implementing CERDAAC, Sidqdeep spent a lot of time emailing team members whenever a form needed to be filled out, explaining what it was that was needed, and how to fill it out. "With CERDAAC, they already know the reason they are logging in, and they are able to complete a task in just a few minutes," she says. "I no longer have to explain the same process over and over again."

Outstanding Service and Support

While the CERDAAC software is easy to use, there are always questions or customizations that may be needed that require a call to the CERDAAC support team. At these times, Sidqdeep finds CERDAAC's support team invaluable. "I

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love working with the CERDAAC team. Whenever I send an email, no matter what question I have, I get an email back right away from a real CERDAAC support person, not just some automated response. The

CERDAAC team are all very responsive and knowledgeable. They get back to me quickly with answers to my questions, and have provided a lot of expertise and guidance that help make our usage of CERDAAC even better."



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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