

Case Study: Myriad Genetics

FDA regulated genetic testing company uses CERDAAC to track and manage medical device equipment



Overview

CERDAAC provides Myriad Genetics a 235% first-year ROI through:

- Moving away from paper and spreadsheets to digitizing calibration and PM (Preventative Maintenance) workflows in a simpler streamlined system
- Alignment between all 4 labs and research facility for one lone source of truth and a unified program
- Providing an auditable service history for all instruments with easy to find records and documentation.
- Avoiding production delays due to instruments being past due for calibration or PM
- Better forecasting to strategically schedule PMs (Preventative Maintenance) so production is not impacted
- Avoiding audit findings from CAP (College of American Pathologists) and CLIA (Clinical Laboratory Improvement Amendments) to maintain compliance





The Challenge: Legacy Software and Lost Paper Trails

Myriad Genetics is a leading genetic testing and precision medicine company dedicated to advancing health and well-being for all. Myriad develops and offers genetic tests that help assess the risk of developing disease or disease progression, and guide treatment decisions across medical specialties where genetic insights can significantly improve patient care and lower healthcare costs.

Wayne Findlay is Myriad Genetics' Supervisor of the Service Engineering group, responsible for maintaining the company's manufacturing assets: including robot platforms, liquid handlers, centrifuges, pipettes, and more. When Findlay joined Myriad, the company was using a combination of paper and a legacy Quality Management Software (QMS) system to track and manage preventive maintenance services.

"We couldn't find things easily and we were not able to upload documents to the system or update them later," says Findlay. "We would have to keep a paper trail and keep paper files of all those documents filled out correctly and keep them updated."

There were a lot of data discrepancies and because we are FDA regulated, we knew it was a problem." As a result, the service engineering team found that preventive maintenance services either were not scheduled on time, or they were being scheduled at times when they should not have been scheduled.

"The system we were using was old and at the end of its lifecycle. We knew we needed to move to something better or would be in trouble, especially as we were growing and acquiring companies, it became even more important." says Findlay.





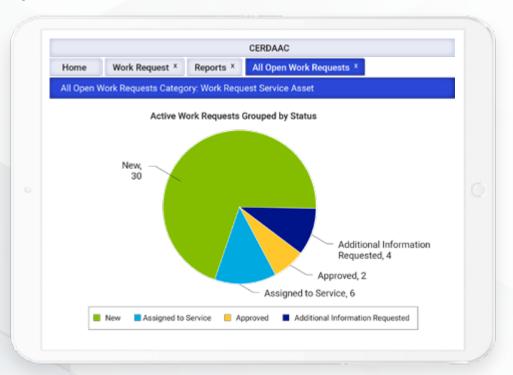
The Solution: CERDAAC Asset Management Software

Searching for a better solution, Findlay discovered that one of Myriad's sister companies was using CERDAAC to track and manage its equipment assets and decided to learn more.

"We already knew of SIMCO's reputation and reliability for service excellence," says Findlay. "That, combined with the fact that one of our companies was already using it, made choosing CERDAAC as our solution an easy decision. We saw the ROI of CERDAAC."

Today, CERDAAC is implemented and accessed regularly by over 400 users across three different sites located in Utah, California, and Ohio. "CERDAAC is better than what we had before," says Findlay.

"Now, it is easy to look up an asset and see all-related service histories, services due, documents, signatures, It's all right there in CERDAAC."



Myriad's Key Requirements

Before implementing CERDAAC, Findlay confirmed that the system would meet the team's requirements.

These included:

- Ability to easily upload all asset related documents, so the team could move away from using paper.
- Accessible by multiple users at different labs and sites around the country to view asset service histories, notifications and more.
- User friendly interface: to minimize training and onboarding time for inexperienced users.
- Easy access and visibility of asset-related documents.

If we uploaded a document and someone wanted to view it, whether it was an auditor or internal audit, or the lab owners of the equipment, we wanted to make sure they had access to it and could get access to the information easily."

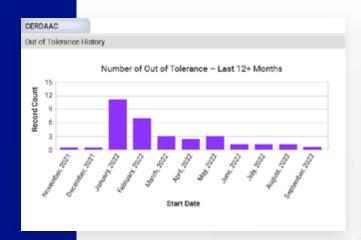


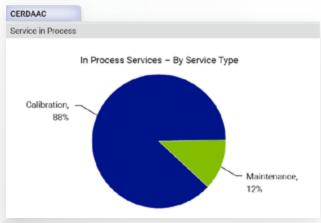
Multiple Locations, One System of Record

Today, the service engineering team and the company's individual labs use CERDAAC to track assets across multiple locations, and to schedule preventive maintenance. "The labs are continually buying new equipment, so we're adding new assets to CERDAAC all the time," says Findlay.

"We use it every day to check the PM status of equipment. With CERDAAC, we can see what services have been completed, and what needs to be done in just a few minutes. No more chasing paper."

When a piece of equipment is moved from one location to another, the system is updated with the information, making it easy to locate an asset when it is due for maintenance. "As long as the lab tells us where they moved it to or who has it, who owns it, we can track it, and we are able to update it easily in CERDAAC."





CERDAAC Streamlines Audit Compliance

Because Myriad Genetics is an FDA regulated company, it is subject to regulatory audits. At those times, CERDAAC is especially useful, both in providing the documentation needed for the audit, and reducing the amount of time it takes to respond to audit requests. "When we have an auditor ask when a PM for a specific asset was performed, and that auditor wants to see the document, we can pull up the answers right away in CERDAAC," says Findlay, "We go right to the asset, right to the service, pull up the document, and then he sees it or prints it out. With the



auditor satisfied with the information, they can continue with the audit. That has been a huge benefit."

CERDAAC Reports Provide Clear Visibility Across Multiple Sites

CERDAAC's reports and dashboards are another key feature Findlay's team finds useful. Reports include key information such as the preventive maintenance services due this month or next; PMs completed, and PMs performed in the past year. Other reports show the number of assets located at each lab, the number of services per lab, and more.

Using CERDAAC reports, Findlay can also track how many times a PM has been overdue for each lab. The labs also have their own separate services that they perform daily or monthly, and use CERDAAC to run reports to identify any due or overdue services.

"I get the reports emailed to me and look over those every day," says Findlay. "Near the end of the year, I get a reminder notification of any outstanding PMs so I can let my team know to get those done. I love reports. We can create and see whatever data we want after it has been added to CERDAAC."





46

When we have an auditor ask when a PM for a specific asset was performed, and that auditor wants to see the document, we can pull up the answers right away in CERDAAC."

The benefit for remote users is another big plus for the team. For example, some labs have a manager or director located in San Francisco, but the manager works out of the Salt Lake location. "The ability for those managers to see what is due in Salt Lake for their job as a director of both labs has helped a lot," says Findlay. "It's definitely a system that we use every day."

For Findlay, the benefits of CERDAAC over the previous system of legacy software and paper are significant.

"The visibility, and the ability of our labs to see what we see every day, is a big benefit."

"Before, we would have to scan or print out a document and give it to the lab, or the auditor or whoever needed it. With CERDAAC, the labs have the visibility they need to continue production and know which equipment is due for preventive maintenance, has a PM service has been completed, and run a report on anything they would like to see. Having that visibility in CERDAAC has been a great tool in our service department."

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

Headquarters:

3131 Jay St Santa Clara, CA 95054