



STREAMLINING FDA COMPLIANCE WITH AUTOMATED MAINTENANCE AND REPORTING PROCESSES

INDUSTRY

Healthcare

ACCRUENT SOLUTIONS

Maintenance Connection - CMMS

"It used to take us three to four hours to go search for paper records. With Maintenance Connection, it's almost immediate. As soon as you run the report, [the information] is there. Now we're able to sit in a conference room and pull it up on the screen for the auditor to view in real time."

– Mike McCormick, Maintenance Manager



Watch Cook Medical share their journey to success on accruent.com

[WATCH THE VIDEO](#)

16,000+
PRODUCTS MANUFACTURED

41
MEDICAL SPECIALTIES

135
COUNTRIES SERVED

2,500
EMPLOYEES

THE COMPANY

Cook Medical is a medical device manufacturing company headquartered in Bloomington, Indiana. Founded in 1963, Cook Medical produces more than 16,000 products for a variety of specialties, ranging from anesthesiology to plastic surgery to transplant surgery.

THE CHALLENGE

With thousands of products produced daily and assets spread across the manufacturing plant, Cook Medical needed a way to track work order status and requests from the floor. A paper-based system caused headaches for everyone from the compliance operator to the manufacturing technicians.

- A time-consuming 100% paper-based maintenance management process
- The need to comply with strict FDA and other government agency regulations
- An inefficient and tedious auditing process that involved digging through filing cabinets to find the paper trail of reports

“The users really like the work order tracking system. They’re able to track what work orders they have, and then we can schedule a lot easier.”



THE SOLUTION

After implementing Maintenance Connection, Cook Medical was able to create an organized database of all assets, past equipment failures, and service history. The company was also able to create a preventive maintenance (PM) schedule, including automated work orders based on historic asset data.

- Work order details on one screen rather than a stack of papers
- Digital calendars to gauge maintenance staff availability and manage labor assignments
- Reporting on every asset that comes into contact with a medical device during the manufacturing process

“For the FDA, the software has to be validated, and Maintenance Connection helped in that validation process. The other thing [the FDA] wants to know is the history of every piece of equipment that touches a medical device. And with Maintenance Connection, it’s at your fingertips.”

THE RESULTS

As a result of using Maintenance Connection, Cook Medical has improved work order tracking, automated maintenance procedures, and ensured compliance with FDA requirements. The company has also streamlined reporting processes, significantly reducing the time spent searching and processing reports. Additionally, the new PM schedule has reduced downtime by alerting technicians that service is needed before equipment failure.

- A reduction in reporting time by 3 to 4 hours due to automated reporting
- Seamless compliance with FDA and other requirements
- Preventive maintenance schedules and alerts that diminish downtime
- Improved efficiencies that help create a better, simpler and more efficient way to treat patients