



Case Study

Medical Device Manufacturer's ISO 13485 Certification Solidifies Culture of Quality

Sunset Healthcare Solutions adopts QT9 QMS to reach their goal of ISO 13485 certification as quickly and painlessly as possible.



Industry

Medical Equipment & Supplies



Founded

2004



Location

Chicago, IL



Employees

50+





Challenge

Sunset Healthcare Solutions needed to implement an ISO 13485-compliant quality management system that would allow them to quickly and easily reach their goal of ISO 13485 certification.

Solution

Sunset chose QT9 QMS based on ease of use and out-of-the-box capabilities.

Explore [QT9 QMS](#)

Results

Sunset was able to achieve ISO 13485 certification in less than one year and, today, enjoys a "culture of quality" throughout the organization.

Quality and Safety

Sunset Healthcare Solutions is a value brand home medical and hospital equipment and supplies manufacturer and distributor. They produce a variety of healthcare OEM products, from CPAP machines and accessories to wound care supplies. The company has seen continued growth since opening its doors in 2004, so much that it has ranked on Inc. 5000's Fastest Growing Companies in America list nine times.

Being a medical device company, end-user experience and safety are always top of mind. Sunset wanted to ensure their commitment to quality and safety was obvious both internally and externally. The first step toward that goal was to become ISO 13485 certified.

QT9 QMS Out-of-the Box Solution

In 2020 Sunset began looking for a new quality management system to better equip them to reach their goal of ISO 13485 certification. At the time, the company was using a different software solution, combined with paper-based processes, to run and manage their quality processes. After a brief search, they ultimately chose to implement QT9 QMS based on ease of use and out-of-the-box capabilities.

Joe Consoli joined Sunset as their new Director of Quality and Regulatory to help build out the new QT9 system. Consoli, who has worked in the quality management arena for more than 30 years, was given the immediate task of moving the company into ISO 13485 compliance and certification.

"When I came into this role," he recalls, "we were able to get our quality data loaded into QT9, get people trained on it, and get us to the point where we were able to go through our pre-audit and then our full ISO 13485 certification with no major nonconformities – all within less than a year."

Sunset's quality team was especially happy that the QT9 system did not require customization to begin using. Consoli noted that QT9 QMS's built-in FDA 21 CFR 11 capabilities, in particular, made the transition easier.

"We didn't have to do any customizations with QT9," he says. "QT9 was flexible enough for us to create a system that matches our requirements, and we were able to push everything quickly through because of that. That ultimately made validations and compliance much easier."



Culture of Quality

Since first using QT9 QMS in 2020, Consoli and team have implemented and are working day-to-day in 18 of the [23-plus modules](#), streamlining and centralizing [document control](#), monitoring and establishing [training](#), and easily following up on [customer feedback](#), [ECNs](#), [corrective actions](#), and [nonconforming products](#).

Using QT9, Sunset has built a company culture where quality is a factor of everything they do. “I believe we’ve created a quality organization throughout our entire company that everyone has bought into,” says Consoli. “We can do things with great velocity with QT9. We are not overly bogged down with approvals or system requirements.”

For easy implementation, uncomplicated user interface, robust capabilities, affordability and top-notch customer support, Consoli believes QT9 QMS can’t be beat.

“We are using something like 17 or 18 of the modules right now, and we implemented only three years ago,” he says. “And customer support is just like the software, you never have to dig for a solution.”

“I have worked in several systems over the years, and out of the box, QT9 is head and shoulders above the rest.”

— *Joe Consoli*
Director of Quality and Regulatory

About QT9 Software

QT9 Software offers both quality management software and ERP job management software. QT9 Quality Management Software is a comprehensive, user-friendly, cloud-based QMS that handles ISO 9001, AS9100, ISO 13485, 21 CFR Part 11, and 21 CFR Part 820 FDA requirements. QT9 ERP has the modules to completely automate and run a business—purchasing, accounting, production, inventory control and sales.

* See the article on the web: <https://qt9qms.com/case-studies/sunset-healthcare-solutions>