

Swan Valley Medical Faces Audits With Confidence

SWAN VALLEY MEDICAL
INCORPORATED



ABOUT THE COMPANY

Swan Valley Medical, Inc. is a privately held medical device and data analytics company. The company provides customized evidence-based solutions to hospitals utilizing predictive analytics (Swan Informatics™) to enable the use of the company's medical device technologies (T-SPeC®). Merging these technologies creates a fundamental change to the historical clinical practice of bladder catheterization that has existed for more than 100 years. Swan's clinical innovative solutions represent a unique opportunity to profoundly change how the world's medical community has treated bladder dysfunction in the treatment of incontinence, retention, and fluid management.

AT A GLANCE

Mission

Maintain an effective QMS to focus on developing new products and manufacturing activities

Best Thing About Arena

All product and quality information can be linked together for easy retrieval

Bottom-Line Impact

Resources can focus more on product development, manufacturing, and infrastructure rather than keeping up with paperwork

Key Benefits

- Streamlined audit processes
- Minimized paperwork mistakes
- Reduced resources required to manage compliance
- Eliminated delays and time-consuming administrative work
- Improved visibility and traceability
- Accelerated change review cycles
- Reduced audit risk
- Improved ability to meet time-to-market targets



BUSINESS CHALLENGES

As an FDA-regulated company, Swan Valley Medical (SVM) is required to show objective evidence to support all processes from design and development through post-market evaluation.

"Swan Valley Medical designs, manufactures, and distributes patented, single-use, urology instruments, and accessories to manage the symptoms of urinary retention or incontinence. We are regulated by the FDA and are certified to ISO 13485:2016. This requires us to maintain a system and detailed records to support our operations and exceptional quality standards," said Swan Valley Medical's Director of Quality Assurance and Regulatory Affairs, Michelle Potvin.

With design and manufacturing operations in Denver, CO, and suppliers across the U.S. and Taiwan, the challenge was—how to improve product information management synchronization across a globally dispersed supply chain and organize evidence of compliance to avoid costly penalties.

Like many medical device companies, SVM was burdened with inefficient, manual, paper-based quality management processes that created compliance risk issues due to their inability to easily find critical documentation. Because information was typically in paper form it was prone to being misplaced, damaged, or inadvertently thrown away.



THE SOLUTION

To ensure operation efficiencies among global teams (internal/external) including engineers, operations, quality teams, supply chain partners, and contract manufacturers, SVM turned to Arena. Implementing Arena's cloud-native QMS solution allowed SVM to eliminate multiple siloed systems for document control and centralize information for a single source of product and quality records.

With automated workflows, bills of materials (BOMs) and files can be imported easily, and engineering

“ Arena provides our team access to a quality management solution that makes it simple to link to documents and records and eliminates time wasted looking for information that might not be there.

—Michelle Potvin, Director of Quality Assurance and Regulatory Affairs, Swan Valley Medical



change orders (ECOs) are reviewed, rejected, or approved without unnecessary delays. This enables effective change release management and accurate revision control processes. Even CAPA resolutions are faster.

"We chose Arena's cloud QMS solution because it allows us easy access to all our BOMs, changes, compliance logs, CAPA reports, SOPs—in one centralized location. Another important feature we like is it has an intuitive web interface that allows us to communicate the latest documentation updates with everyone in our supply chain. It also helps our teams on the manufacturing floor access the most current documentation—avoiding the use of down-rev documents," said Potvin.

“Using a QMS is a simple solution to quality maintenance, especially in a regulated industry. Arena doesn't stop at document control or CAPA. The software covers all aspects of the QMS, so an audit is less stressful.

—Michelle Potvin, Director of Quality Assurance and Regulatory Affairs, Swan Valley Medical

KEY BENEFITS

Arena helped SVM eliminate product development delays and quality issues that were caused by old manual-based engineering change processes. With a connected product lifecycle management and quality management system, SVM can quickly process ECOs—BOMs and files can be imported quickly and efficiently so products in design can meet go-live deadlines. By allowing teams to simultaneously review change orders and gain visibility regarding bottlenecks and prior actions, they've been able to accelerate change review cycles. Arena QMS also makes audit preparation and responsiveness easy because everything is consolidated into one system. Auditors are happy to see a structured system where all information is easily retrievable. Users can access information at their fingertips, without deep dives to find what they need. "When the system is set up to flow with your process, finding documents and records is fast and easy. Spending more time discussing opportunities for improvement instead of defending against nonconformance issues is more productive," said Potvin.

