Case Study

# Medical Devices

arena

# Discover How Arena Helped Swan Valley Medical Face Auditors With Confidence

## BUSINESS CHALLENGES

**Company**
Swan Valley Medical

**Location**
Bigfork, Montana

**Industry**
Medical Devices

**Business Challenges**
- Miscommunication amongst dispersed supply chain
- Inability to organize product information
- Change order chaos

**Solutions**
Arena PLM BOMControl
Arena Projects
Arena Quality

**Business Benefits**
- Eliminated errors associated with paper processes
- Heightened change order process visibility
- Lowered change order complications

**ROI Results**
- Streamlined audit processes
- Limited ECO mistakes
- Reduced resources necessary to manage compliance

Swan Valley Medical (SVM) is a privately held medical device company founded in 2006 by a retired urologist and engineer/entrepreneur. The company's focus is on development and commercialization of sophisticated urological surgical instruments, as well as introducing new approaches and technologies to enhance and improve upon existing devices and procedures.

"Swan Valley Medical has developed a line of unique, patented, single-use surgical instruments and accessories for application in the field of urology," said Swan Valley Medical's Chief Operating Officer Laurence Sampson. "The Company's first urological instrument was an innovative, patented cystostomy device for placement of suprapubic catheters in adult patients. The product, which has received regulatory approvals in the United States, European Union and Canada, can be used as part of a regimen to manage the symptoms of urinary retention or incontinence.

Founded in Montana, SVM now has design and manufacturing operations in Denver with suppliers all over the country, including one overseas in Taiwan. Sampson began to realize that the company now desperately needed a better way to manage product information to facilitate synchronization across a globally dispersed supply chain.

"It had become difficult to disseminate the information to both internal employees and suppliers," explained Sampson. "When using a paper system to record quality process data, it is increasingly difficult, in a timely manner, to accurately recall the correction evidence in the context of an external audit," said Sampson. "At some point in time it became necessary to get better structure and organization around the documentation."

To meet FDA and other regulations, Sampson knew SVM needed a professional system to manage information to organize evidence of compliance and avoid costly penalties and brand damage. Unfortunately for Sampson, SVM was burdened with inefficient paper-based manual processes that resulted in potential compliance exposure due to misplacing critical documentation.

"When you get hit with an audit finding either because; you're missing information, or the information provided is inaccurate, it can be difficult to recover," explained Sampson. "Reprocessing the entire CAPA log can take a couple hundred hours."

He continued, "But I'll tell you what, once you have an audit finding like that happen, you never want it to happen again. You end up with staff doing CAPA remediation for the next two months and then nothing gets done but the CAPA remediation."

## SOLUTIONS

To ensure operation efficiencies among global (internal and external) teams — including engineers, operations, supply chain partners, and contract manufacturers — Sampson turned to Arena Solutions.

"We chose Arena because it had such an intuitive web interface that allows us to touch everyone in our supply chain and always provide current updates of documents," said Sampson. "It also helps our people on

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the manufacturing floor because Arena provides them with the latest documentation without any concern about down rev documents out on the floor."

With Arena BOMControl, BOMs and files alike can be imported with simple tools. ECOs are reviewed, approved, or rejected without interruptions, enabling release management/revision control with minimal administrative work and distractions. By allowing teams to simultaneously review the status of change orders — with visibility into holdups and notifications of approvals — development delays are reduced. Sampson also believes Arena makes audits easier and less time consuming because it's a cloud-based solution that consolidates all compliance information in one centralized system.

"Another reason we integrated Arena was centered around document control," said Sampson. "Arena gave us an appropriate level of control without spending a lot of money on infrastructure. All the systems that we have had in the past — CAPA systems, Non-conforming Material Report (NCMRs), complaint logs — have been paper systems. As such, the interlinking of the different systems has been difficult to follow and understand. With Arena BOMControl, our operation people constantly remark how having workflow integrated into a software tool makes standard operating procedures (SOPs) easier to understand. Arena forces you through the logic of what you are doing and straightens out a lot of the workflow."

## BUSINESS RESULTS

According to Sampson, Arena eliminated the time-consuming complications of managing unwieldy change order packages by formalizing the engineering change request and engineering change order (ECO) process with an intuitive cloud-based product lifecycle management (PLM) solution. Engineering teams now have easy access to searchable product information from a password-protected cloud-based interface.

"ECO cycles are definitely quicker because when you go to review the ECO the data is right in front of you," said Sampson. "Same with CAPAs or any of these other processes."

Once Sampson implemented Arena PLM, he immediately implemented CAPA into the stystem. "We've also added in an impact, a root cause analysis and risk management observation process. Each one of these different processes can call the other ones or demand that another process be used. They can also be linked together so that when you get an audit you have a tightly integrated cross linked evidence chain for whatever problem you're dealing with," said Sampson. "It's really been great."

Sampson knew that a PLM solution that embeds quality with a framework that supports future integrations and add-ons is bound to offer a superior approach to managing quality and reducing risk. And that's why three of the top five medical device companies rely on Arena's multi-tenant cloud-based PLM solution.

Find out how Arena can help you achieve success and take your company from chaos to calm. Sign up for a demo at **www.arenasolutions.com/plm-demo**