

Case Study

Medical Device





Company

Apical Instruments

Location

Redwood City, California

Industry

Medical Device

Business Challenges

- Risk of FDA exposure
- Lack of lifecycle visibility
- Expenses incurred from archaic QMS methods

Solution

Arena's All-in-one PLM/QMS Solution

Business Benefits

- Streamlined ECO processes
- Eliminated expensive IT teams
- Improved compliance approval success

ROI Results

- ECOs went from months to days
- Saved over \$10,000 from eliminating manual sharing of files
- Saved \$100,000 by removing IT costs

Why Quality Execs Prefer an All-In-One Product Development Platform

BUSINESS CHALLENGES



Located in Redwood City, CA Apical Instruments is a medical device contract manufacturer that handles all stages of the development process from conceptualization to production.

With over 25 years of experience in the medical device regulatory affairs and quality assurance fields, Apical Instruments Director of Regulatory Affairs & Quality Assurance Kim Khoe knows a thing or two about the keys to quality success.

Kim's quality experience includes setting up companies' quality management systems, hosting FDA and 3rd party audits, as well as auditing medical device manufacturers, having been a lead auditor for a European Notified Body. She has also filed a handful of FDA 510(k) submissions resulting in clearances and obtained CE marks for various products.

According to Khoe, the benefits of contracting with Apical include real dividends in production of effective product, reduced development time, lower overhead count, and quicker regulatory approvals - all to enable a delivered complete project.

"Contracting with Apical to efficiently handle the design, prototyping and manufacturing eliminates your need to organize a staff to support these efforts," says Khoe. Khoe, who has been using Arena since 2004, has implemented the solution for several international companies with great success.

To meet FDA and other regulations, Khoe knew she must be able to manage information professionally to show evidence of compliance and avoid costly penalties and brand damage. Early in her career, she experienced firsthand the pain and burden of inefficient paper-based manual processes and the risk of compliance exposure caused by misplaced critical documentation that impeded her ability to prove mandatory compliance.

Khoe and CEO Bruno Strul agree that having a product lifecycle management (PLM) system by itself — while an upgrade from manual processes — can still present problems if the solution is a siloed system that requires linking to another solution. Khoe points out that due to the lack of visibility with siloed systems, problems can start snowballing fast. The classical case is key cross-functional team members are unaware of changes due to insufficient transparency with a problem only presenting itself just before shipping to market.

SOLUTIONS

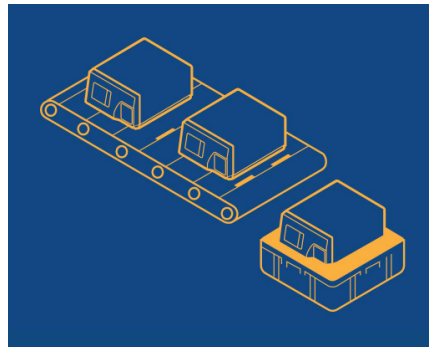
To ensure superior product lifecycle visibility and enhanced collaboration amongst team members, Khoe turned to Arena Solutions because of its all-in-one solution with an embedded quality management solution (QMS), application lifecycle management (ALM) and connection to powerful component databases.

“I didn’t need to hire a team to manage the infrastructure associated with an on-premise siloed system anymore. I now only needed one person to help me which kept my overhead costs low.”

— Bruno Strul, Chief Executive Officer, Apical Instruments

“Arena can do it all: manage your bill of materials (BOMs), quality system, documents, device returns, nonconformance and your entire CAPA.”

— Kim Khoe, Director of Regulatory Affairs & Quality Assurance, Apical Instruments



“I always insisted upon Arena,” says Khoe. “Arena can do it all: manage your bill of materials (BOMs), quality system, documents, device returns, nonconformance and your entire CAPA.”

Another benefit is Arena’s superior customer service.

“Where Arena stood out was that it seemed the response time of all other PLM systems was lacking,” says Khoe, “I’m not a software person, but Arena made it so easy for me. Arena’s customer service has always been there. I know someone at another life science company

who was evaluating PLM systems and I recommended Arena. Customer service at Arena can’t be beat.”

According to Khoe, facets to the ROI that Arena provides customers are numerous and include:

- Engineering change order (ECO) turnaround time shrunk from months to days.
- Saved money by removing the need to scan, save and email big documents separately via email. “Customers can just log into Arena, sign the ECO, and then they’re done.”

Khoe also experienced a ROI with reduced costs to meeting compliance mandates. According to Khoe, Arena makes audits easier and less time consuming with a cloud-based solution that consolidates all compliance information in one centralized system. The solution streamlines management of BOMs, the design history file (DHF), the device master record (DMR) and change orders.

“I can give an example that a complete audit trail is in Arena. We had a customer that needed proof that the product was ROHS compliant,” says Khoe. “And pulling the ROHS documents could have cost us \$20,000 for this particular job. But with Arena, it saved us all that money because we had the documentation at our fingertips.”

BUSINESS RESULTS

But the bottom line for Khoe, who sings the praises of Arena to her colleagues at other medical companies, is that Arena provides an all-in-one solution that not only saves time and money but ensures quality.

Khoe points out that even today, some medical device companies tend to operate in silos with defined stage-gate handoff points during the product design process; however, this outdated approach can have a very negative impact on new product introduction (NPI).

Due to the lack of visibility with siloed systems, Khoe had seen firsthand how problems started snowballing fast; for instance, finding out at the very last minute that a certain part had gone End of Life (EOL) or does not meet the compliance requirements can cause a lot of problems. But if the company has an all-in-one PLM solution with embedded quality and an integrated electronic component database, an alternative part that would have worked just as well could have been sourced by engineering.

“With Arena, we now have BOMs and quality system documents in one place. Everybody has access to it,” says Khoe. “I am not making copies of documents throughout the whole company. Even though we’re small.”

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