ABOUT THE COMPANY

Apical Instruments is a medical device company located in Redwood City, California, on the San Francisco Peninsula. They have partnered with companies to design, develop, and manufacture quality medical device products. The benefits of utilizing Apical’s services include real dividends in production of effective products, reduced development time, lower overhead count, and quicker regulatory approvals—all to enable a delivered complete project.

With over 30 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.

AT A GLANCE

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

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

Bottom-Line Impact
- Reduced ECO cycles from months to days
- Saved over $10,000 by eliminating manual sharing of files
- Recuperated $100,000 by removing IT costs
BUSINESS CHALLENGES

Kim’s quality experience includes setting up companies’ quality management systems, hosting FDA and third-party audits, and auditing medical device manufacturers, having been a lead auditor for a European Notified Body. She has also filed many 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. Prior to working at Apical, Khoe successfully implemented Arena for several international companies.

To meet FDA and other regulations, Khoe knew she must be able to manage information in a controlled and secure manner to show evidence of compliance and avoid costly consequences, penalties, and brand damage. Early in her career, Khoe experienced the pain and burden of inefficient paper-based manual processes, which led to increased compliance risks and exposure caused by misplaced critical documentation that made it hard 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 PLM system is disconnected from the quality management system. The lack of visibility with siloed systems creates problems that can start snowballing fast. The classic case is when key cross-functional team members are unaware of changes due to insufficient transparency—and a problem only presents itself just before shipping to market.

THE SOLUTION

To ensure superior product lifecycle visibility and enhanced collaboration among team members, Khoe turned to Arena because of its unified solution with an embedded quality management system (QMS) and connection to powerful component databases.

“I didn't need to hire a team to manage the infrastructure associated with an on-premises 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,” shared Khoe. “It can manage our bill of materials (BOMs), quality system, documents, device returns, nonconformances, and our entire corrective and preventive action process.”
Another benefit is Arena’s customer service. “Arena’s customer support program and responsiveness really stood out,” says Khoe, “I’m not a software expert and Arena’s customer service team has always provided great support.”

Our return on investment (ROI) for Arena is based on:

• Accelerated turnaround time from months to days for engineering change orders (ECOs).
• Reduced time and eliminated inefficiencies spent on scanning and sharing large documents and ECOs.
• Streamlined ECO process which allowed teams to easily access and approve documentation in real time.

Additional ROI was provided by reducing the cost of compliance. Arena made it much easier to address our audits by having a single system to manage product, quality, and compliance information. This single system streamlines management of BOMs, the design history file (DHF), the device master record (DMR), and change orders.

“We had a customer that needed proof that our product was RoHS compliant,” says Khoe. “Searching for, and pulling the necessary RoHS information would have cost us about $20,000 for this job. But Arena’s connected compliance records provided us with the necessary documentation quickly.”

KEY BENEFITS

Arena provides a unified product development solution that not only saves time and money—but ensures quality.

With Khoe’s past experience, she shared that some medical device companies tend to operate in silos with defined stage-gate handoff points during the product design process. This has a negative impact on new product introduction (NPI).

Due to the lack of visibility with disconnected systems, past problems grew exponentially. For instance, last-minute discoveries that a certain part had gone end of life (EOL), or did not meet the compliance requirements, caused a lot of problems.

With Arena, we were able to add traceability from product design records to quality records and component compliance information—reducing our research time dramatically.

“Arena’s unified product development system gives our teams easy access to information when they need it,” concluded Khoe. “It’s been a key reason we’ve been able to scale as our business grows and has also simplified our ability to meet regulatory requirements.”

“Arena can do it all. It can manage your bill of materials (BOMs), quality system, documents, device returns, nonconformances, and our entire corrective and preventive action process.”

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