

# Achieving Commercialization and Compliance Success



## ABOUT THE COMPANY

Potrero Medical is a predictive health company developing the next generation of medical devices with smart sensors and artificial intelligence. The company emerged out of Theranova, a medical device technology incubator focused on tackling the biggest challenges in healthcare. Today, Potrero Medical is working on preventing acute kidney injury while also helping frontline workers combat the spread of COVID-19 with their [Accuryn Monitoring System](#). This system enables remote monitoring by automating urine output and providing real-time intra-abdominal pressure and core body temperature, which is vital for patients not only in critical care but also burn, trauma, and cardiac surgery. Since this system offers remote monitoring, it limits the number of times a healthcare worker needs to enter a patient room which dramatically helps hospitals decrease use of personal protective equipment. Long term, the company is training algorithms from this data to help clinicians predict and prevent acute kidney injury and abdominal compartment syndrome.

## AT A GLANCE

### Mission

Help clinicians transform patient care by developing a predictive technology platform for the early detection of critical illnesses

### Best Thing About Arena

Product-focused QMS

### Bottom-Line Impact

Helped Potrero achieve product commercialization and compliance goals

### Key Benefits

- Product-centric QMS with validation package ensures compliance
- Improved ECO quality by approximately 25%
- Shortened ECO cycle time by around 30%
- Training compliance improved from about 80% to greater than 98%
- Component nonconformance improved by nearly 20%
- Complaint cycle time decreased by 25%



## BUSINESS CHALLENGES



As a highly regulated medical device company, Potrero needed to ensure compliance with the International Standardization Organization (ISO), Food and Drug Administration (FDA), and European Union (EU) to

achieve commercialization success. "I was brought on to evaluate quality processes and systems as we prepared to launch our first product because we didn't have a system that was robust enough for new product introduction and compliance processes," stated Sanjay Banerjee, COO for Potrero Medical. "We had FDA clearance, but our product was not commercialized yet and our current manual processes would not scale or hold up to the scrutiny of audits."

Product and quality information was managed using paper-based processes where bills of materials (BOMs) were documented on paper and then uploaded into a manufacturing system. Engineering change orders (ECOs) were also reviewed manually with limited supplier communication. The team at Potrero needed a scalable quality management system (QMS) that could support their growing product development and compliance needs while helping them address and pass audits.

## THE SOLUTION

Having prior experience using Arena QMS, Mr. Banerjee knew that Arena was the right fit for the company, stating: "Arena QMS is a true lifecycle management system that is better than the typical document-focused QMS solutions I have experienced. Being able to manage BOMs and changes along with quality processes is a major advantage."

Also, as a cloud-based system, Arena QMS didn't require a huge IT infrastructure investment or a lengthy implementation. "We started engaging with Arena Solutions in January and by March we were live using the system," said Banerjee. "We're using Arena for all training management, supplier management, design controls, engineering change management, regulatory compliance, quality records, and operations processes."

Arena QMS connects quality records directly to the product design in a single system. This allows Potrero to document and track closed-loop quality processes for device master records (DMRs), design history files (DHF), training records, and nonconformance reports (NCR) in context to the entire product record and BOM. "We have all the phases of design and development managed in Arena QMS," stated Banerjee. "This includes secure access for our suppliers, which are located globally, allowing them to be notified immediately of any change and ensure their system is up to date."



## KEY BENEFITS

Since implementing Arena QMS, Potrero has seen significant improvements across product design and quality, reporting the following benefits:

- Change orders approved during the first review improved by approximately 25%
- ECO cycle time accelerated by approximately 30%
- Training compliance improved from about 80% to greater than 98%
- Component nonconformance improved by nearly 20%
- Complaint resolution cycle time decreased by 25%

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—Sanjay Banerjee, COO, Potrero Medical

## ROBUST VALIDATION AND COMPLIANCE PROCESSES

Arena QMS provided the robust platform that Potrero was looking for to meet its audit inspection requirements. After commercializing their product, they had their first FDA inspection and didn't receive any warnings or 483 observations. Potrero demonstrated that their quality system and issue resolution processes improved using Arena QMS. Furthermore, Arena QMS was instrumental during a Medical Device Single Audit Program (MDSAP) ISO 134845 audit that resulted in Potrero receiving a CE mark. “Auditors recognized that using Arena eliminated the need to review controls, processes, or ask certain questions,” noted Banerjee.

A key benefit of using Arena's cloud-based QMS involves software validation. Arena Validate provides a validation package for medical device customers to help them speed compliance. It covers the critical elements of document management, design controls, change management, electronic signatures, quality management, and requirements management. [Arena Validate](#) was a significant differentiator because it saves Potrero considerable time and resources needed for validation efforts. “The fact that we receive validation maintenance packages that hold up to audit scrutiny is another huge benefit of having Arena QMS,” said Banerjee. “When we show Arena to the auditors, any concerns about validation are eliminated.”

With Arena QMS, Potrero has confidence in its quality and compliance processes that couldn't be realized using manual processes and has a solid, scalable platform to continue its growth and innovation in developing devices for the prevention of acute kidney injury and other critical diseases.