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CASE STUDY

Software Medical Device Manufacturing Company Launches New Quality Management System in Record Time

ARC-One Achieves Quality, Regulatory, and Safety Goals with ComplianceQuest's Market-Leading QHSE

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—Jared McDonley, Director of Regulatory Affairs and Quality Systems

Background

ARC-One is a software medical device manufacturing company headquartered in Miramar, Florida. Founded as a collaboration between the Red Cross and One Blood. The software tracks each unit of donated blood from collection to transfusion, improving the blood donation process, and ensuring safety.

Challenge

As a recently formed start-up, ARC-One needed to have a fully functioning quality management and health safety system before officially opening its doors. Initial planning and strategizing for the quality system began in late 2019, with a launch date of April 2020.

"One of our biggest challenges and goals was that we needed to be fully compliant and ready for any type of FDA inspection on opening day. We couldn't have any gaps in compliance," said Jared McDonley, Director of Regulatory Affairs and Quality Systems.

McDonley, who previously served as Director of Quality Systems at One Blood, was able to port over the blood center's quality and safety operating procedures to ARC-One. However, he needed a new enterprise quality and safety management software platform; ideally, one that was more aligned with the needs of a medical device company.

Solution/Results

After extensive market research, ComplianceQuest, a cloud-based enterprise quality and safety management system (QHSE) built on the Salesforce platform, was chosen for its flexibility, scalability, and in-depth knowledge of the medical device space.

"Our install base is going to be exceptionally large, and ComplianceQuest gave us the compliance and growth potential we were looking for," said McDonley. "We knew they had a scalable platform and could ensure we had the infrastructure to follow exceptionally specific regulations from the get-go."

Accelerated Roll-Out Reduces Time, Effort, Costs

ARC-One was in a tight time crunch due to late-stage funding, and the speed of deployment was a critical factor. "From the very first phone call, we could tell that ComplianceQuest knew the challenges that lay ahead of us. We shared our timeline, and they agreed to an accelerated roll-out schedule," said McDonley.

But the implementation time was only one factor. To McDonley, it was also essential to cut down on user validation time. "ComplianceQuest already had solutions in place that could decrease our overall end-user validation time. Because of their experience working with life sciences companies and the regulated market, we were able to reduce end-user validation time and meet every milestone."

CHALLENGES

- New venture required 100% regulatory compliance on day one
- Short roll-out time
- Extensive customization needs
- Highly regulated industry

VALUE CREATED

- 360-degree view of quality and compliance
- Improved FDA reporting processes
- Seamless collaboration & communication
- Supplier evaluation capabilities

SOLUTIONS

- EQMS
- Change
- Document
- Training
- Nonconformance
- CAPA

Software That's Customizable and Beautiful Out of the Box

ARC-One's first goal was to implement the document, training, and change control modules. "These are the backbone of compliance, and we were successful by having these modules in place on day one," noted McDonley. "It's been a solid, collaborative relationship to ensure we hit our targets."validation time and meet every milestone."

One of the characteristics ARC-One liked about ComplianceQuest's software was its off-the-shelf functionality. "Many of their modules are beautiful right out of the box," said McDonley. "Customization always introduces potential issues and longer times to validate. My goal was to pick the product that required the least amount of adjustment, and ComplianceQuest fit that bill. We've only requested customization when necessary."

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—**Jared McDonley,** Director of Regulatory Affairs and Quality Systems

McDonley focused his customization needs on the document control module. "I went into document control, knowing how I wanted everything laid out in exceptional detail. With the FDA, if it's not documented, it didn't happen. The customizations we requested gave us exactly what we wanted with our record retention, storage, and organization procedures and ensured we would be compliant."

McDonley was also impressed with the supplier module, which tracked how well suppliers met their specifications and provided ways to either reject vendors or place them on contingency plans.

"We were hoping ComplianceQuest could mirror our existing policies and procedures. When we saw the out-of-the-box supplier configuration, it was better than we could have imagined and even provided additional functionalities."

Complaints Module Allows for Direct Reporting to FDA

Medical device reporting is a specific subset of the quality control process. ComplianceQuest offers a reporting feature within its Complaints module that fits perfectly with ARC-One's needs. The module provides best practices for life sciences combined with decision tree functionality, which supports the identification of adverse events and report types by various regions.

"The out-of-the-box features help us determine if an event is reportable. If it is, a task is created, and you are prompted to fill in details that the FDA requires. Once that's complete, it will create the XML file to load into the FDA's reporting system," explained McDonley. "This was wild to me."

Seamless Productivity and Communication

"If your quality system is doing a great job, you're increasing productivity, quality, and safety all at the same time," said McDonley. "However, a common perception of what we do in quality control and assurance is to create bottlenecks. So, the more seamless we can work with various departments, the easier it is for us to be helpful versus a hindrance."

ComplianceQuest helped ARC-One move from a paper-routing system to an electronic system. "In the past, routing approvals were paper-based. We had to walk a single piece of paper from desk to desk," said McDonley. "Today, changes happen quickly with cloud-based revisions and electronic signatures. Our new system is vastly simplified, which makes communication and cooperation a breeze."

The roll-out was completed within the promised timeline, and ARC-One launched in April 2020.

"Looking at ComplianceQuest's website, you get the impression they are a really big company, but when you work with them, you are treated as if they were a small company that cares about each customer," concluded McDonley. "ComplianceQuest identified their success with our success. They went the extra mile and made sure we met our quality goals and launch date, which speaks volumes."

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"We knew they had a scalable platform and would ensure precise regulatory compliance from the get-go."

—Jared McDonley, *Director of Regulatory Affairs and Quality Systems*

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COMPLIANCEQUEST
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About ComplianceQuest

ComplianceQuest is the fastest growing, 100% modern cloud Enterprise Quality and Safety Management System (QHSE) natively built and run on the Salesforce platform. Our unified QHSE solutions help our customers of all sizes deliver quality products and services in the safest, most sustainable way by mitigating risk, problems, and inefficiencies while protecting customers, employees, suppliers, and brand.

For more information, or to request a demo with a ComplianceQuest expert, contact ComplianceQuest today.

- Visit www.compliancequest.com
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