REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

RCA's Outsourced QA Leadership Benefits Emerging Device Maker

Client:

Distributor with goals to launch a manufactured medical device

Industry:

Medical Device

Business Challenge:

Set-up and management oversight of QMS for emerging device maker with financial constraints

Project Timeline:

6 months

About QMS for Medical Devices

The FDA Quality System (QS) regulation applies to finished device manufacturers who intend to commercially distribute medical devices. Commonly referred to a Quality Management Systems (QMS), these required aspects include US FDA 21CRF820 *Quality System Regulation*, US FDA 21CFR806 *Medical Device Correction and Removals*, US FDA 21CFR803 *Medical Device Reporting*, 21CFR807 *Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices*, 21CFR801 *Labeling*, and ISO 13485: 2016 *Medical devices -- Quality management systems -- Requirements for regulatory purposes Medical Devices.*

Client Challenge

The savvy team had a business plan in place, a solid IP platform and a manufacturing plan, but they lacked a regulatory (RA) and quality pathway. Since they were bootstrapping the company, they implemented off-the-shelf QMS software, but later realized their approach fell short of a complete solution.

RCA Approach

Regulatory Compliance Associates (RCA) was engaged to conduct a gap analysis and address shortcomings between their current systems against the RA and QMS requirements. RCA began a steady process of backfilling where they needed help, such as matching the purchased standard operating procedures with their business needs and remediating their product development process in accordance with the developing QMS. As the launch date for the new product approached, RCA helped them implement CAPA and a complaint system, along with an internal audit plan.

- Management representative role
- QMS oversight
    - Standard Operating Procedures
    - Document Control and Quality Records
    - Design History Record Review
    - Design Change Process
    - Post Production Monitoring
    - Product Complaint Process
    - Service & Repair Process
- Internal QMS audits
- Training of internal quality resources
- FDA inspection planning and training
- Quality System Registration to ISO 13485
- Quality engineering support including new electronics

"We would absolutely recommend RCA to set up and manage a quality system. We couldn't afford to hire personnel with RCA's expertise and our engagement allows us to tap into their experts as needed while we focus on growing the company."

—Vice President Operations

To accomplish the resulting QMS system, RCA provided the company with experts in quality systems and quality engineering/electronics.

Results

With RCA's outsourced QA expertise and their internal staff, the company was able to launch the product, comply with all regulations, pass regulatory audits, and implement their Quality Management System without hiring expensive executives. With RCA's backfilling their compliance gaps, the company was able to salvage their investment in the QMS software. Additionally, because RCA set up a payment plan with fixed monthly fees, the company could meet their cash flow requirements.

After RCA's initial engagement, the product experienced commercial success. As the company continued to grow and scale, RCA was retained for ongoing support as their outsourced QA/RA manager, working hand-in-hand to augment their capabilities, while keeping their expenses to a manageable level. As the company sales grew, it became attractive to investors and was acquired by one of the top 100 leading medical technology companies.