

REGULATORY COMPLIANCE ASSOCIATES®

A Nelson Labs company

Medical Device Services



Who We Are

At Regulatory Compliance Associates Inc (RCA), we provide worldwide services to the pharmaceutical, medical device, biologics, combination products, and compounding pharmacies industries for resolution of compliance and regulatory challenges.

Our backgrounds include every facet of R&D, operations, regulatory affairs, quality and manufacturing. We are used to working on the front lines and thriving in the scrutiny of FDA and globally regulated companies.

As your partners, we can navigate the potential minefield of regulatory compliance with insight, hindsight, and the clear advantage of our unique expertise and experience.



Founded in 2000



Headquartered in Southeastern Wisconsin



Acquired by Sotera Health in 2021



Backed by over 500 industry SME's



ISO 9001:2015 Certified



Regulatory Affairs

Regulatory Affairs is our backbone, and we handle more submissions in a month than many manufacturers do in a lifetime. From assisting with small projects all the way to outsourcing your entire Regulatory Affairs department. We have experience working with the FDA, global regulatory bodies and / or agencies, and notified bodies worldwide. You can count on us for in-depth and up-to-date insights which increase speed-to-market.



- Global Regulatory Strategy & Pre-Submissions Support
- International / Domestic Regulatory Submissions
- Establishment Registration & Device Listing
- US Agent Services

- Medical Device Reporting / Adverse Event Reporting
- Recall Management
- Re-submission Assessment & Remediation
- Post Market Surveillance

- Product Portfolio Review
- QMS Gap Assessments
- Staff Augmentation and Support
- Remediation and Implementation



Compliance Assurance

Increasingly, Life Science companies are feeling the pressure of greater scrutiny by regulators, and are responding by developing sustainable compliance strategies. Whether it's preparing for an audit, developing a response to an FDA finding, or remediation of an adverse event, RCA can help.

- Assessments
- Internal Audits, CMO & Supplier Audits
- Mock Inspections
- Regulatory Agency Action Response
- Notified Body Responses





Quality Assurance

RCA's consultants are Quality experts with experience spanning start-ups to international corporations. We know firsthand how to achieve, maintain, and improve quality, and we excel in transferring this knowledge to your organization.

- Outsourced Quality Support
- Staff Augmentation
- Quality System Implementation
- Risk Management (ISO 14971)
- ISO 13485, 21 CFR Part 820

“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 them as needed while we focus on growing the company”

—Vice President of Operations



Remediation & Strategy Support

RCA is widely recognized for its ability to help companies successfully resolve complex regulatory challenges. Our value goes beyond the initial response by helping companies execute their plans. Our unique expertise and experience make partnering with us a competitive differentiator in the remediation space.

- Quality System Remediation
- DHF & Technical File Remediation
- Data Integrity Services
- Regulatory Action Remediation
- Manufacturing Process, Equipment, Facility & Utility Validation
- Part 11 and Computerized System Validation



Strategic Consulting

Whether it's a strategy, technical plan, or project, RCA's worldwide experience can help ensure a successful mix of people and product so your project is on time, on budget, and you're never embroiled in a costly mistake.

- Manufacturing Optimization & Aging Facilities
- New Product Development
- Product Life Cycle Management
- Staffing Support
- Mergers & Acquisition / Due Diligence

Why Choose RCA?

- We are widely recognized within the life science industry and by global regulatory agencies for our ability to help companies successfully deal with complex regulatory challenges.
- By mining regulatory intelligence, we continuously evaluate FDA's and other regulatory agencies current thinking and leverages thought leadership networks to advocate for our clients.
- We know a quality or compliance crisis can significantly impact your business. We have the experience to manage them.
- We have the know-how and proven approach to navigate Warning Letters, Consent Decrees and other situations.
- We know how to partner with your executive, legal and communication teams.
- We support management to assist with the growing and changing concerns.
- We help navigate the storm and manage the impact to your business.

Regulatory Compliance Associates Inc

Your Go-To Source

When The FDA Calls



REGULATORY SUBMISSIONS IN 196 COUNTRIES /DEPENDENCIES | ENGAGEMENTS ON 4 CONTINENTS | OFFICES AT 4 LOCATIONS

ISO 9001 CERTIFIED

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