



RCA | Regulatory
Compliance
Associates®

Medical Device Consulting Info Sheet

Safeguarding Global Health.
- with every new product approved.

www.rcainc.com

Who We Are

At Regulatory Compliance Associates® (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



Expertise backed by
over 500 industry
subject matter
experts



ISO 9001:2015
Certified



Regulatory Support for New Product Development

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
- Part 11 and Computerized System Validation
- Laboratory Oversight & Support



Strategic Consulting

Whether it's a strategy, technical plan, or project, RCA's worldwide Medical Device 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; Equipment, Facility & Utility Validation
- New Product Development
- Product Life Cycle Management
- Staffing Support
- Mergers & Acquisition / Due Diligence

Who We Are



Safeguarding Global Health.

Sotera Health Company, along with its three best-in-class businesses – Sterigenics®, Nordion® and Nelson Labs®, is a leading global provider of mission-critical end-to-end sterilization solutions and lab testing and advisory services for the healthcare industry. With a combined tenure across our businesses of nearly 200 years and our industry-recognized scientific and technological expertise, we help to ensure the safety of over 190 million patients and healthcare practitioners around the world every year.

Sotera Offers



Laboratory Testing

Nelson Labs is a global leader in outsourced microbiological and analytical chemistry testing for the medical devices and pharmaceutical industries.



Sterilization

Sterigenics is a global provider of outsourced terminal sterilization and irradiation services for the medical device, pharmaceutical, food safety and advanced applications markets.



Expert Consulting Services

RCA is a global provider of regulatory, compliance, and quality consulting services for life science companies.



Cobalt-60 and Irradiation Systems

Nordion is a global leader that provides reliable, long-term, end-to-end Cobalt-60 supply and services.

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ISO 9001 Certified