REGULATORY COMPLIANCE ASSOCIATES® INC

Wellness for Business®

# RCA Service Offerings

Regulatory Compliance Associates® Inc. (RCA) provides worldwide services to the pharmaceutical, biologic, sterile compounding, biotechnology, and medical device industries for resolution of compliance and regulatory challenges.

We understand the complexities of running a life science business and possess areas of expertise that 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 negotiate 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, with offices in West Central Florida; North Central Colorado; and Central Eastern Europe
- Expertise backed by over 500 industry subject matter experts

## RCA Resources

Effective: From our Senior Executives to our tactical team members, all of our resources have been tested in the line of fire.

Efficient: Using the right level of resource for the right task is central to efficient execution. We have the resources depth and breadth to support all of the project needs.

Economical: Using the right resource for the right task ensures the most economical approach without sacrificing effectiveness or efficiency.

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## Regulatory Affairs

Regulatory Affairs is our backbone and we fully understand the complexities of the life science industry. Our expertise spans all facets and levels of Regulatory Affairs.

- Global Regulatory Strategies
- Meetings and Briefing Packages
- US and Global Submissions (IND, ANDA, NDA, de Novo, 510(k) and PMA)
- Dossier Management
- eCTD and Electronic Submissions
- Outsourced Regulatory Affairs

## Compliance Assurance

Life Science Companies are feeling the pressure of greater oversight by regulators, and sometimes they respond by developing sustainable compliance strategies. Whether it's preparing for an audit, developing a response to an FDA finding, or remediating an adverse event, RCA can help.

- Assessments (GMP, ISO, PAI)
- Audits (Internal, Supplier, CMO)
- Regulatory Agency Action Response
- FDA Inspection Readiness and Training

## Quality Assurance

Our services include strategy development, implementations, and identification of quality metrics to ensure continuous improvement, aligning with your business needs and goals. Our consultants are quality experts with experience spanning major corporations and start-ups.

- Quality System Implementation
- MDSAP Preparedness
- Risk Management (ISO 14971, ICH09)
- CAPA and Complaint Systems
- Outsourced Quality Services

## Remediation Strategy & Support

We have the know-how and proven approach to navigate Warning Letters, Consent Decrees and other situations. We will partner with your executive, legal and communication teams and support management with their growing and changing concerns.

- Quality System Remediation
- DHF and Technical File Remediation
- Data Integrity
- Regulatory Action Remediation
- Validation Services

## Strategic Consulting

Whether it's a regulatory strategy for how to get your drug or device approved, or Due Diligence to support an Acquisition, RCA's Global 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 Process Optimization and Aging Facilities
- New Product Development
- Product Life Cycle Management
- Staffing Support
- Mergers & Acquisitions / Due Diligence