REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Pharmaceutical Services

At Regulatory Compliance Associates Inc. (RCA) we understand the complexities of the Pharmaceutical and Biopharmaceutical Industries. Our expertise spans all facets of R&D, Manufacturing Operations, Regulatory Affairs, Quality Assurance and Compliance. We are used to working on the front lines with our clients to help them navigate in a highly regulated industry.

As your partners, we can negotiate the potential minefield of pharmaceuticals with insight, hindsight, and the clear advantage of our breadth and depth of knowledge and experience.

REPRESENTATIVE EXAMPLES OF OUR EXPERTISE		
Product Categories	**Product Families (Indications)**	**Product Types**
Sterile Parenteral Injectables	Anesthesiology	Small Molecules
Lyophilized and Aseptic Powder Fill	Analgesia	Biologics
Tablets/Capsules	Anti-infectives	Biosimilars
Ready-To-Use Liquids	Oncology	Combination Products
Novel Formulations	Critical Care	*In vitro* Diagnostics

RCA enlists over 500 top industry experts, blending FDA veterans and seasoned regulatory affairs leaders. Who we help:

- Start-ups and Virtual Life Science Companies that want to leverage the benefits of outsourced services
- Fortune 100 multi-national companies to start-ups
- Companies new to FDA and pharmaceutical regulations
- Law firms seeking experts in remediation of 483's, Warning Letters, Consent Decrees or Import bans
- Private equity and law firms seeking technical due diligence

Regulatory Affairs

New Product Support

- Global Regulatory Strategy
  - Global Submissions
- Meetings and Briefing Packages
  - Pre-IND, Pre-NDA
  - (BPD) Type-3
  - End of Phase 2
  - Advisory Committee
  - Type A, B or C
- US and Global Submissions
  - IND, DMF, BLA, ANDA
  - NDA: 505(b)(1) & 505(b)(2) and Combination Products
  - Orphan Designation, Fast Track and Expedited Review
  - Marketing Authorization Application (MAA) Clinical Reviews
  - European Pharmacopoeia & Certificates of Suitability (CEPs)

"RCA has an understanding of food and drug law coupled with the knowledge of the inner workings of FDA"

Life Cycle Management

- Dossier Management
- Change Control
  - eCTD and Electronic Submission Capabilities to U.S., Canada and EU
  - DMF Amendments and Annual Reports
  - DMF Conversions to eCTD
  - Annual Reports and PADARs
  - Supplements Changes Being Effective: CBE 0 & CBE 30
  - Prior Approval Supplements (PAS)
- Type I and Type II Variations (EU)
- Abbreviated New Drug Application (ANDA)

*Changes introduced during LCM of any drug product

Other Regulatory Services

RCA can also help with your unique Regulatory needs. We understand that it's not just the submissions and inspections where companies might need assistance, sometimes it's additional items needed to support your business operations.

- Outsourced Regulatory Affairs and Staff Augmentation
- DMF: (New or eCTD Conversion)
- US Agent Services
- Regulatory Gap Assessment
- Due Diligence
- Site Registration
- Regulatory Affairs Training
- Electronic eCTD Preparation and Submission

Compliance Assurance

- Due Diligence
  - Regulatory & Quality Due Diligence
  - Facility / Equipment Assessment
  - Personnel Assessment
  - Post-Merger Integration
- 21 CFR Part 11, Annex 11 Assessment
- 21 CFR Part 210 & 211 Assessment
- cGLP Assessment or Training
- Internal Audits, Contract Manufacturer Audits, Supplier Audits
- FDA Inspection Readiness & Training
- Regulatory Agency Action Response
  - 483 Response
  - Warning Letter
  - Consent Decree
  - Import Bans

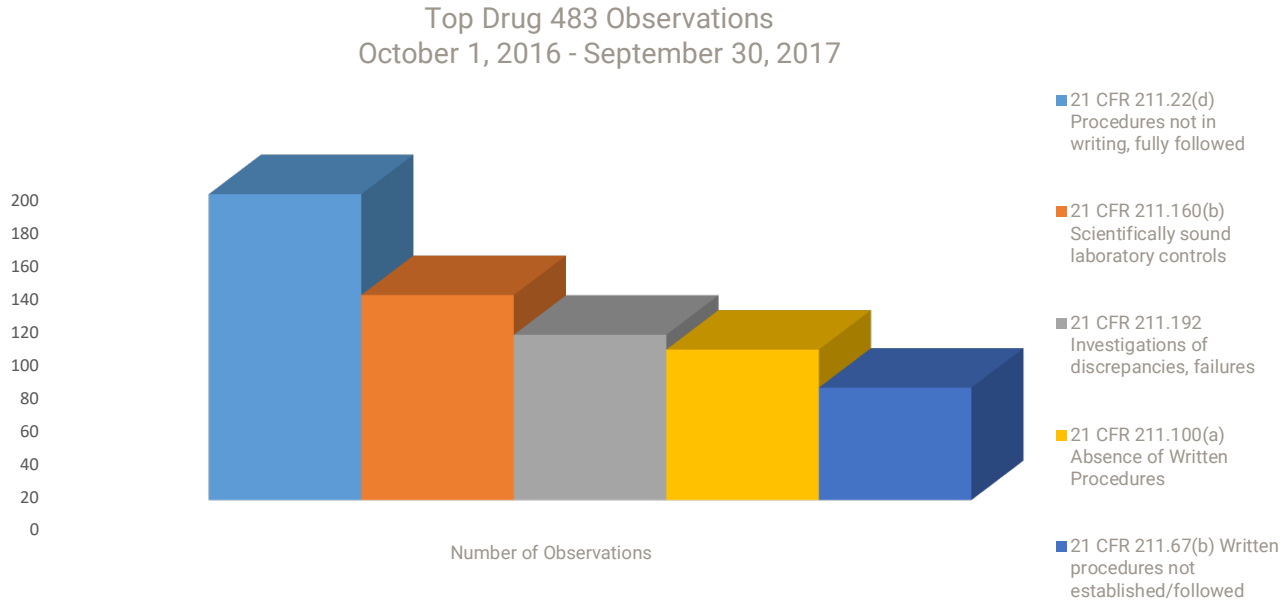
Quality Assurance

- Outsourced Quality Support
- Quality System Implementation
- Quality System Remediation / Improvement
- Risk Management ICH Q9
- CAPA and Complaint System
- 21 CFR Part 210 and 211
- Computerized System Validation
- Laboratory Support
    - SOP Development
    - Method Transfer
    - Method Validation

> *"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 Operations

Remediation Strategy and Support

- 21 CFR Part 210 & 211 Remediation
- Oversight Services for Manufacturing and Quality Services
- Data Integrity Services
- Regulatory Action Remediation
    - 483 Remediation
    - Warning Letter Remediation
    - Consent Decree Remediation
- Manufacturing Process Equipment, Facility and Utility Validation
- Part 11 and Computerized System Validation
- Laboratory Support



Strategic Consulting

- Manufacturing Process Optimization
- Automation and Aging Facilities
- Staffing Needs
  - Staff Augmentation
  - Project Team
- Change Management
  - Changes to Comply with Standard
  - Cost Reduction
  - New Supplier
  - Changes to Address Complaints
- Quality System Automation Using Software
- Master Validation Plan
- Mergers & Acquisition / Due Diligence
  - Regulatory & Quality Due Diligence
  - Facility/Equipment Assessment
  - Personnel Assessment
  - Post-Merger Integration

"RCA not only remediated our warning letter, but they also helped prepare our teams for an upcoming audit. We received no observations during the next FDA inspection."

—VP of Quality

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 and Consent Decrees.
- 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.

Quick Facts About RCA:

- Founded in 2000
- Headquartered in Southeastern Wisconsin with offices in West Central Florida, Northern Colorado & Central Eastern Europe
- Expertise backed by over 500 industry and FDA subject matter experts
- Regulatory Submissions in 196 different countries / dependencies
- Engagements on four continents
- ISO 9001 Certified

"You won't find a more talented team, a more personable group, or one more dedicated to your success than Regulatory Compliance Associates."

—Senior Manager of Corporate Reliability Engineering

RCA SERVES *the* WORLD

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

ISO 9001 CERTIFIED

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