REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Regulatory Affairs Services

New Product Development, Regulatory Submission and Life Cycle Management Support

New Product Development

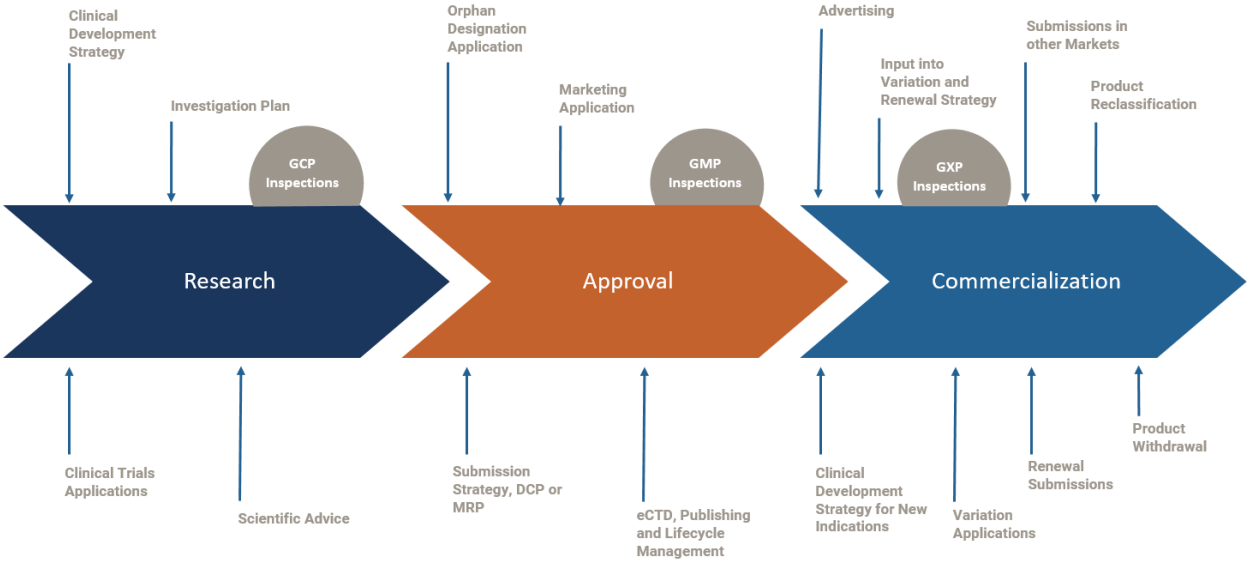
In the complex and increasingly regulated Pharmaceutical Industry, Regulatory Compliance Associates (RCA) can assist you with New Product Development Regulatory Support. From early development stage and seeking guidance for FDA meetings, to later stage regulatory strategy and global alignment of submissions and dossiers, RCA is your one-stop source for regulatory expertise. We provide services to support all types of product applications.

- Meetings and Briefing Packagers
  - Pre-IND, Pre-NDA, Type A, B or C, and others
  - BLA Meetings
  - Advisory Meetings
  - Orphan Designation, Fast Track and Expedited Review
- Global Submissions/Dossiers (Europe and Canada)
- US Submissions (IND, DMF, BLA, ANDA, NDA) and Combination Products

Life Cycle Management

Perhaps your company needs help with dossier content management during the life cycle of the drug. RCA can help by coupling regulatory strategy with document management and eCTD publishing. Even if you just need additional staff to help during transitional periods, RCA provides knowledgeable, experienced regulatory affairs associates who can help.

- Dossier/Application Management
  - Amendments, 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)
- Global Change Control
- Staff Augmentation
- eCTD and Electronic Submission Capabilities to US, Canada and EU



Preparation and Training

Anticipating an inspection soon and want to improve your staff's preparedness or knowledge base? RCA can help during peak work loads, inspections, or even during transitional periods of systems upgrades or high turnover. Let RCA provide Training and Support to get your company on the right track.

- FDA Readiness Inspections
- Front (Inspection) + Back (Control) Room Logistics
- Tools and Process Flow Diagramming
- Document Control and Tracking
- Facility Tour Preparation
- Personnel Behavior and Coaching
- Mock Inspection/Gap Assessment/Identifying High Risks
- Leverage learnings, internally across company
- Regulatory Affairs Training

Additional 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
- New Dossier and DMF or Conversion to eCTD Format
- Regulatory Gap Assessment and Due Diligence
- Electronic eCTD Preparation and Submission
- US Agent Services
- Internal Audits
- Site Registrations
- Regulatory Affairs Training

Compliance Assurance

RCA is recognized in the Pharmaceutical Industry for our abilities and expertise in the field of Regulatory Compliance. From company mergers to regulatory action letters, when you only get one chance to get it right, RCA can provide the experience needed to ensure success.

- Mergers & Acquisition / Due Diligence
  - Regulatory Due Diligence
  - Quality Due Diligence
  - Facility/Equipment Assessment and Gap Analyses
  - Personnel Assessment
  - Post-Merger Integration
- Regulatory Agency Action Response
  - 483 Response
  - Warning Letter
  - Consent Decree
  - Import Bans

"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 9001:2008 CERTIFIED

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