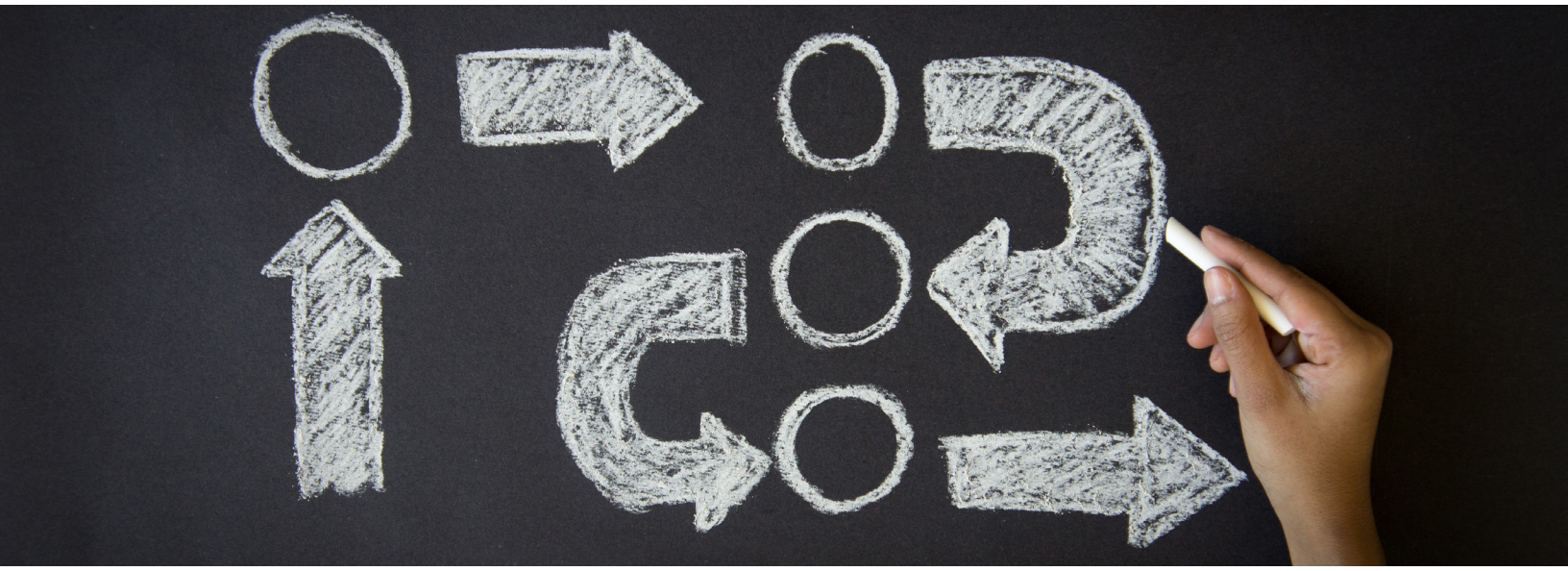
REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®



Challenges with Regulatory Submissions?

Regulatory Compliance Associates® Inc. (RCA) develops regulatory strategy, implements plans, handles submissions, and remediates regulatory challenges. Regulatory Affairs is our backbone, and we handle more submissions in a month than many manufacturers do in a lifetime. RCA has experience working with notified bodies worldwide, therefore you can count on us for in-depth and up-to-date insights which increase speed-to-market.

RCA can assist your organization throughout the entire submission process by initially providing a comprehensive regulatory strategy which will describe how the product will likely be regulated by the FDA or any other global Regulatory Agency / Body, including:

- Relevant product code(s)
- Applicable classification / regulation
- Predicate device(s) if applicable
- Relevant Standards and / or Guidance documents applicable to the product
- The required performance and / or clinical testing
- The most likely regulatory pathway(s) that may be considered for obtaining clearance and / or approval in the United States market
- Preparation of the Regulatory Submission to FDA and/or global Regulatory Agency / Body

Once the regulatory strategy and submission is complete, RCA will remain available to answer any questions the FDA may raise during the review period.

AREAS OF EXPERTISE:

- Anesthesiology
- Cardiovascular
- Combination Devices
- Dental
- Ear, Nose and Throat
- Gastroenterology/Urology
- General Hospital
- Hospital Hardware
- In Vitro Diagnostics
- Obstetrics/Gynecology
- Ophthalmic
- Orthopedic
- Radiology
- Surgical Devices
- Wound Care

RCA GLOBAL MARKET ENTRY REGULATORY SERVICES:

- Product Classification Reports
- Global Regulatory Strategy
- Pre-Submission (Pre-Sub) Packages / Pre-Submission Meetings with FDA
  - Pre-Sub [510(k)]
  - Pre-Sub [De Novo]
  - Pre-Sub [PMA]
- 513(g) Request
- Regulatory Procedures
- US Agent Services
  - Facility Registration
  - Device Listing

RCA GLOBAL REGULATORY SUBMISSIONS SERVICES:

- Site Registration
- Traditional Regulatory Pathways
  - Premarket Notification [i.e., 510(k)]
    - Traditional 510(k)
    - Special 510(k)
    - Abbreviated 510(k)
- Premarket Approval (PMA)
  - Traditional (PMA)
  - PMA Supplement & Amendments
    - PMA Supplement (180 days)
    - Special PMA Supplement -- Changes Being Effected
    - 30-day Notice and 135 PMA Supplement
    - PMA Manufacturing Site Change Supplement
    - Annual (periodic) Report or 30-day Supplements
- Modular (PMA)
- Product Development Process
  - Product Development Protocol
- Innovative Regulatory Pathways
  - De Novo Request
    - 510(k) to De Novo
    - Direct De Novo
  - Humanitarian Use Device (HUD)
  - Humanitarian Device Exemption (HDE)
- International Regulatory Package
- Submission Intervention & Remediation
  - Response to FDA Additional Information (AI) Request

Who We Serve:

U.S. & International Medical Device Industry

Our Submission Expertise is Broad and Deep

- We work with companies spanning start-ups to Fortune 100 multinationals
- Companies with proprietary products considering expansion or acquisition
- Domestic & International companies expanding to new geographic markets or seeking local assistance
- Organizations new to medical devices and the submissions process
- Experienced medical device companies seeking to outsource the submissions process
- Respected private equity and law firms seeking technical expertise for their clients

International Regulatory Submissions / Technical Product Dossiers / CE Marking

- US Food and Drug Administration (FDA)
- Health Canada
- European Union (EU)
- Australian Therapeutic Goods Administration (TGA)
- China Food and Drug Administration (CFDA)
- Japan Pharmaceutical and Medical Devices Agency (PMDA) / Ministry of Health, Labour & Welfare (MHLW)
- Brazil Agencia Nacional de Vigilancia Sanitaria (ANVISA)
- Mexico Federal Commission for the Protection against Sanitary Risk (COFEPRIS)
- South Korea Ministry of Food and Drug Safety (MFDS)
- And many other global regulatory agencies worldwide

RCA's Regulatory Affairs Advantage

RCA integrates with your established Regulatory Affairs department to assist and provide greater bandwidth by augmenting staff:

- We support projects with large workload and/or tight timelines
- RCA can take responsibility for product regulatory affairs, allowing the staff to focus on business-critical deliverables, or vice versa
- RCA can act as the "virtual" Regulatory Affairs group, supporting all your regulatory needs including:
    - Strategic planning
    - Technical writing and generation of submissions/supplements/DHFs/etc.
    - FDA communications and meetings

FDA Quality System Requirements / ISO 13485

A robust Quality System compliant with FDA Quality System Regulation/Medical Device Good Manufacturing Practices (21 CFR Part 820) and/or ISO 13485 is the foundational cornerstone to ensure devices are designed, developed, and manufactured according to Good Manufacturing Practices (GMP). As a device maker it is necessary to implement and maintain a quality management system that complies with FDA Quality System Regulation (QSR) and Good Manufacturing Practices (GMP). RCA is uniquely qualified to help you ensure compliance with 21 QSR Part 820 and/or ISO 13485 to prepare your organization for inspections / audits by the FDA and other global Regulatory Agencies / Bodies.

Need Help with FDA Compliance?

Whether struggling with a submission strategy and execution or dealing with regulatory compliance, Regulatory Compliance Associates® Inc. stands ready to support you and your company. Armed with consultants serious about compliance and having years in the trenches as quality and regulatory leaders, RCA can help you establish a sustainable compliance solution and remain at the forefront of the ever-evolving regulatory landscape.

RCA helps medical device companies with regulatory compliance and market access in the United States and other markets worldwide.

- US FDA regulatory strategy and classification
- FDA 510(k) preparation and interface with FDA
- Quality Systems implementation, auditing, and remediation US FDA Agent Services for medical device manufacturer not based in the United States
- Medical device new product development
- Mock Inspections
- Complaint Files / Medical Device Reporting
- Design Controls
- Design History File Creation / Remediation

BENEFITS OF OUTSOURCING REGULATORY AFFAIRS:

1) Avoids the need to hire, train, support, supervise, and potentially terminate employees.

2) Provides a flexible workforce at your disposal, because we right size for your business, scaling with your needs.

3) RCA connects you to SMEs with the right expertise at the right time, without the overhead.