Regulatory Compliance Associates®
A Nelson Labs company

Challenges with Regulatory Submissions?

Regulatory Compliance Associates® (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.

Who We Serve

U.S. & International Medical Device Industry

- 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

New Product Approval Support

Regulatory changes are one of the most troublesome challenges facing medical device companies seeking approval of a new product. RCA guides you throughout the research and approval process as you meet strict and changing regulations both domestically and globally. We offer a wide range of new product approval support services to help you comply with industry demands and plan mass commercialization, including:

- ISO 13485 and FDA compliance evaluations
- FDA Pre-Submission
- FDA Pre-Submissions support include 513(g) requests and product classifications
- FDA 510(k), DeNovo, and PMA submissions
- Technical writing such as 510(k) submissions, explanation letters and clinical reviews

Post Approval Support

Our team of industry experts is here to make sure your medical device remains dependable and effective, even after it's placed on the market. Our post-approval support solutions are designed to ensure that your product is always in compliance, with services including:

- Medical Device Reporting/Adverse Event Reporting
- Recall Management
- Re-Submission Assessment & Remediation
- Post Market Surveillance

Other Regulatory Services

At RCA, we understand that no two medical device companies have the same regulatory needs. From small special projects to ongoing assistance, we offer a range of additional regulatory services and will customize a consulting solution based on your product and unique business demands. Some of our many additional services include:

- Outsourced regulatory affairs
- Regulatory affairs training programs
- Regulatory due diligence
- Regulatory gap assessment

International Regulatory Submissions/ Technical Product Dossiers/CE Marking

- US Food and Drug Administration (FDA)
- Health Canada (HC)
- 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

EU Medical Device Regulations (MDR)

If your company is looking to sell medical devices in Europe, your products will need to comply with new EU Medical Device Regulation (MDR) requirements. Our expertise allows us to assist you in EU MDR compliance through the following services:

- A comprehensive review of product portfolios and current certificate expiry dates
- Gap assessment
- Remediation and implementation of an EU MDR compliance plan
- MDR Device classification
- Assembly of MDR technical documentation
- Clinical Evaluation Report
- Post Market Surveillance/Post Market Clinical Follow-up documentation

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Regulatory Compliance Associates Inc., a Nelson Labs company, is a recognized leader in life science consulting, known for their expertise in navigating complex regulatory and compliance challenges.