

Regulatory Affairs

Working with You to Achieve Your Regulatory Goals

It Begins with Strategy

At RCRI, the regulatory process starts with a well thought out strategy.

After a thorough review, we will develop a strategic regulatory plan tailored to your specific product. This plan will take your business objectives and factors about markets, countries, and regulatory agencies into account. It is the strategy that defines an efficient and effective pathway to market approval and guides the regulatory tactics.

RCRI has extensive experience with the U.S. FDA and international regulatory bodies. Therefore, you can count on submissions that move smoothly through the approval process

Creating a Comprehensive Regulatory Plan

A comprehensive regulatory plan involves addressing many elements ranging from the relatively simple to the complex. A comprehensive regulatory plan should address:

- Intended use and indications for the product.
- Key product claims and how they will be supported.
- Possible predicate devices/products.
- Country specific regulatory pathways.
- Product classification in targeted countries.
- Labeling requirements.
- Pertinent regulatory guidance documents.
- Standards and directives.
- Biocompatibility testing.
- Preclinical studies.
- Clinical studies.
- Manufacturing sites.
- Export requirements and/or conditions.
- Possible regulatory risks.
- Contingency plans.

Go Global with Less Effort

Reaching beyond the U.S. market may seem like a daunting task requiring submissions, presentations, and negotiations in foreign languages in countries with different business cultures.

RCRI will guide you through the regulatory process in major international markets and develop a plan for securing approvals in countries most amenable to your product.

U.S. Regulatory Capabilities

- Strategic planning
- Premarket Notification (510k)
- Premarket Approval Application (PMA)
- Investigational Device Exemption (IDE)
- Investigational New Drug (IND)
- New Drug Application (NDA)
- Biologic Licensing Application (BLA)
- Master files
- Combination products
- Humanitarian Device (HUD)
- Humanitarian Device Exemption (HDE)
- Medical Device Reporting (MDR) and complaint handling
- Product Development Protocol (PDP)
- Labeling
- Interpretation of standards and guidelines
- Preparation and representation at FDA advisory panels and regulatory agency meetings
- Postmarket surveillance protocols
- Registration and licensing
- Import certificates and registration
- Expert reports

International Regulatory Capabilities

- Strategic international planning
- Master files
- Design dossiers
- Technical documentation and files
- Expert reports
- Labeling
- Interpretation of standards and guidelines
- Export certificates and registrations
- Registration and licensing
- Vigilance reporting
- Postmarket reporting

RCRI has achieved successful approvals with major regulatory agencies and notified bodies worldwide including but not limited to:

- European Notified Bodies (CE mark).
- Therapeutic Products Programme (TPP) (Canada).
- Medicines and Healthcare Products Regulatory Agency (MHRA) (United Kingdom).
- Ministry of Health, Labour and Welfare (Japan).
- Therapeutic Goods Administration (TGA) (Australia).
- Ministry of Health (Mexico).
- State Food and Drug Administration (SFDA) (China).

Get More For Your Regulatory Submissions

By integrating expertise from multiple functional areas, RCRI can help you get more from your regulatory submissions.

The RCRI regulatory staff also works closely with in-house clinical experts to determine optimal study designs, statistical techniques, and endpoints that can save you time and money.

Integration also means that you can achieve more than just market approval from regulatory submissions. You can also gain robust data to support key product claims.

This comprehensive approach means the difference between an average and an outstanding product launch.

Implementation

We are Creative

When it comes to the development and implementation of regulatory strategies, RCRI goes beyond the routine.

RCRI knows how to develop novel and targeted regulatory strategies to win approval. As professional consultants, we can develop different options and discuss the risk/benefits of each alternative along with possible fallback positions.

Even with a unique or challenging drug/device combination product, you do not have to get caught up in competing regulatory jurisdictions or derailed with complicated testing protocols.

With an appropriate regulatory strategy in place, the implementation process will go smoothly.

We can leverage long-standing relationships with regulatory officials to shepherd regulatory documentation through the appropriate channels in the U.S. and abroad.

Similarly, RCRI can expedite the regulatory process by interpreting communications from regulatory agencies and negotiating with regulatory officials.

We are Flexible

Each company requires a different set of resources. RCRI is committed to customizing services to meet your goals and objectives.

We can assist you in many capacities, from providing extra resources for a particular project, to starting from a prototype and doing it all.

RCRI is flexible. In whatever capacity you choose, we will advocate for your product to achieve regulatory approval.

Our Mission is to Serve our Clients with Knowledge, Integrity, and Ingenuity

At RCRI, we are proud of our record in providing integrated Contract Research Organization (CRO) services to the medical device, IVD, and biologics, and combination products industries. Since our inception in 1999, RCRI has helped more than 400 companies worldwide translate their product plans into successful revenue generating businesses. Our clients range from development stage start-ups to the largest Fortune 500 companies.

Whether it is a single task or a complex multi-faceted project, you can count on the highly qualified professionals at RCRI.

Getting Started

Getting started is as easy as making a phone call. During an introductory session, we will discuss and evaluate your needs.

RCRI professionals will start a project with a simple work order. Or, we can develop a formal proposal with detailed timelines, milestones, deliverables, and budgets.

RCRI is committed to helping companies get their products to market approval more quickly, efficiently, and effectively.

Please contact us to discuss how we can assist you.