



Quality Systems and Compliance



Meeting your specific quality and compliance needs

The Regulatory & Clinical Research Institute (RCRI) goes beyond off-the-shelf quality systems and compliance. We take the specifics of your company and product into account up front, so you get a compliant quality system designed for ease of use and efficiency.

Because RCRI quality and regulatory experts work together closely, you can start product development with the confidence that your quality system will meet or exceed regulatory requirements and stand up to the rigors of a manufacturing environment over the long-term.

Our experts have the training and experience required to develop quality systems best suited for specific sectors of the medical products industry including medical devices, IVDs, biologics, pharmaceuticals, and combination products.

We understand global requirements and can design quality systems that comply with U.S. FDA regulations as well as those of the European Union, Japan, Canada, and Australia.

RCRI can assist you with your quality and compliance needs at any point in the process of taking a product from concept to market.



Quality and compliance capabilities

Quality systems

RCRI offers comprehensive quality services and will develop and implement systems that conform to a variety of standards and regulations including the following:

- Quality System Regulation (QSR).
- Good Laboratory Practice (GLP).
- Current Good Manufacturing Practice (cGMP).
- Current Good Tissue Practice (cGTP).
- International Organization for Standardization (ISO).

RCRI will also develop and implement:

- Standard Operating Procedures (SOPs).
- Document and data control systems.
- Design control and risk management procedures.
- Employee training programs.
- Vendor/subcontractor assessment systems.



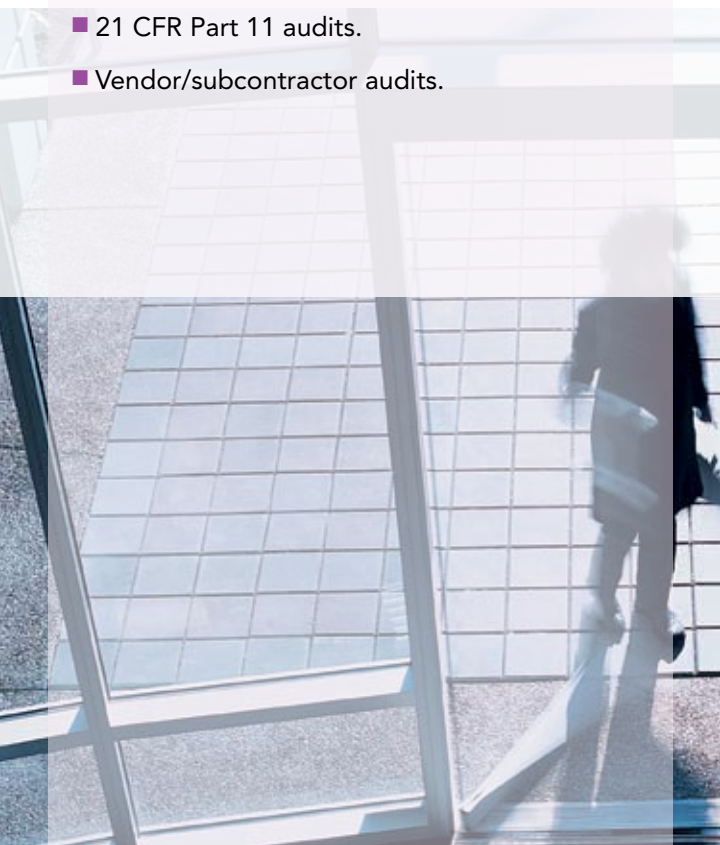
Quality and compliance capabilities

Audits

RCRI will conduct gap analyses of existing quality systems and compliance throughout the product life cycle.

We will also help you prepare for audits or conduct various types of audits including:

- Internal audits.
- ISO 9001/13485 audits.
- GLP audits.
- QSR/cGMP audits.
- Good Clinical Practice (GCP) audits.
- Clinical study audits.
- 21 CFR Part 11 audits.
- Vendor/subcontractor audits.



We will respond to your postmarket quality and compliance needs by assessing and preparing:

- Corrective and preventive action systems.
- Early warning feedback systems.
- Complaint handling systems.
- Medical Device Reports (MDRs).
- Vigilance reports.
- Health hazard evaluations.
- Product recalls.



Quality and compliance capabilities

Corrective actions

In the event that corrective actions are needed, RCRI will develop a strategy and implement a plan to conduct:

- Safety alerts.
- Product recalls.

We will also prepare responses to:

- Warning letters.
- U.S. FDA 483 observations.
- Notified body nonconformances.



Increased efficiency through integrated functions

RCRI quality professionals collaborate with regulatory and clinical colleagues to develop quality systems and compliance programs that work across functional areas and multiple product lines.

It is our goal to ensure that the systems and programs used in product design, preclinical/clinical testing, manufacturing, and marketing are aligned and meet established standards.

This integrated approach to quality systems and compliance will help ensure that a product is favorably assessed in audits and/or due diligence reviews.

We strive to develop quality systems that meet or exceed global regulatory requirements that will work well as you add markets and products to your business portfolio.



We are flexible

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

RCRI can assist you in many capacities. We can function as your quality system manager or provide supplemental resources for a specific project. We can work at your company or off-site depending on the project and your needs.

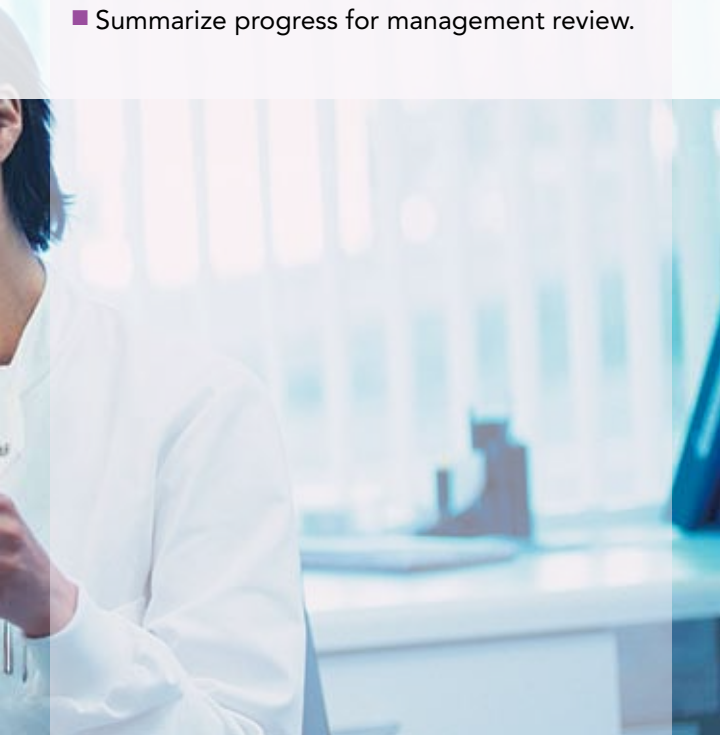
RCRI is flexible. In whatever capacity you choose, you can count on the work of highly qualified RCRI professionals.



Quality systems and compliance checklist

Use the following checklist to help track your progress on quality and compliance tasks:

- Identify quality system standards and regulations that apply to your business.
- Conduct a gap analysis for compliance.
- Develop missing documentation.
- Implement and train employees on the new documentation.
- Monitor ongoing effectiveness of the quality system.
- Address issues with corrective and preventive actions.
- Summarize progress for management review.



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, pharmaceutical, IVD, and biologics 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.



RCRI is a leader in providing integrated CRO services to the medical device, IVD, biologics, and combination products industries.

RCRI is ISO 9001:2008 certified.



ISO 9001:2008
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