



**Regulatory and  
Quality Systems  
services**

 **RCRI**<sup>®</sup>

Expert advisors. Exact practices.

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strategic consulting throughout the product lifecycle

Navigating today's **compliance** world is complex



establish globally-accepted regulatory and quality systems

obtain regulatory approval

maintain compliance

**regulatory strategy**

**negotiating approval**

**quality strategy**

the right path to market can make the difference between gaining first mover advantage or missing the target patient population

regulatory agencies worldwide have differing expectations for presenting evidence for approvals

recalls, 483's, warning letters, adverse event reporting all drive closer scrutiny by regulatory agencies and more enforcement actions

■ ■ RCRI **Regulatory and Quality** strategies  
■ ■ help you chart a course for success.

# Considerations for success



Success starts with the end in mind. Designing comprehensive, programs with integrated regulatory and quality considerations is crucial to successful product launches and keeping your product in the market.



Integrate regulatory and quality strategies.



Use risk based systems to address real issues.



Maintain innovative plans, flexible enough to address specific device nuances.



Research & understand regulatory body hot buttons



**Expert** Advisors. Exact Practices.

## RCRI Solutions

- intended use
- claims & claim support
- regulatory pathways
- labeling



- quality systems design
- document & data control systems
- training programs

- submissions
- applications
- design dossiers
- registration & licensing



- vendors
- clinical site
- quality
- BIMO
- due diligence
- Medical Device Reporting (MDR)
- risk analysis
- post-market vigilance



# Expert advisors. Exact practices.

## technology & product experience

- ablation products
- biologic devices
- combination products
- device delivery systems
- dental implants
- dermal fillers
- imaging technologies
- implantable devices
- IVD
- IVF products
- wound healing: meshes/fabrics
- neurostimulators
- neurovascular devices
- orthopedic/spine implants
- pacing leads
- peripheral vascular devices
- pulmonary products
- stents
- surgical instruments
- surgical technologies
- tissue adhesives & sealants
- urinary incontinence bulking agents

## therapeutic experience

- Cardiology
- Cardiovascular
- CNS/PNS
- Dental
- Dermatology
- Diabetes
- ENT
- Gynecology
- Gastroenterology
- Hematology/Oncology
- Neurology
- Neurosurgery
- Neurovascular
- Ophthalmology
- Orthopedics
- Pain management
- Peripheral vascular
- Pulmonology
- Urology
- Spine
- Wound healing

## expertise

- auditing
- case report design
- CER development
- clinical feasibility
- clinical operations
- clinical strategy
- data flow optimization
- database development
- epidemiology
- medical writing
- protocol development
- publication planning
- quality strategy
- regulatory negotiations
- regulatory strategy
- reimbursement strategy
- statistical strategy
- statistics
- strategic data management planning
- submission preparation