



# **REGULATORY OFFERINGS**

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## **IT'S A CHANGING WORLD, ARE YOU READY?**

The timing and pace of regulatory changes are amongst the most difficult challenges facing medical device and pharmaceutical companies today. RISQ Management is expertly positioned to provide our clients with on-going reviews, updates, and maintaining of regulatory intelligence.

## **WHY NEED A REGULATORY EXPERT?**

RISQ Management has worked in every medical device clinical specialty and pharmaceuticals/biologics, Class I, Class II, Class III, we've executed on them all, whether you face domestic or international challenges - or both! RISQ Management is prepared to become an extension of yours to get the job done. Our high-performing, adaptive team is ready for any task!



FDA  
APPROVED

## WHAT RISQ MANAGEMENT OFFERS

RISQ Management has worked in a multitude of clinical specialties for medical devices/pharmaceuticals and offers the leadership and expertise to get to market. We provide an all-inclusive service; some key offerings include:

- Development of regulatory strategy project development, pre-market submissions, and FDA review
- Approval/clearance support
- Product labeling and Instructions for Use development
- Clinical Evaluation Report (CER)
- Commercialization support
- Post-market changes

*“RISQ Management experts are meticulously selected to provide extensive knowledge and experience that matches your company needs to prevent delays in bringing products to market, and you will maximize returns on your investment.”*

## DO YOU REALLY NEED REGULATORY COMPLIANCE?

The short answer is yes you do, but why? Today government agencies recognize standards the medical companies must comply with in order to ensure that quality systems oversee safe manufacturing and clinical trial oversight; these systems must include established processes for regulatory compliance and risk mitigation.

RISQ Management offers a unique approach that ensures consistency and accuracy throughout the entire organization.

- Audits are a part of our complete quality system service and cover a range of areas.

## WHAT ABOUT POST-MARKET?

RISQ Management offers a wide variety of post-market support to our clients to ensure product compliance throughout commercialization.

- We offer change control evaluation and can help you determine the effect these changes have on active submissions:
  - Manufacturing Changes
  - Design Changes
  - Labeling Changes
- Annual Progress Reports
- Complaint handling

