QA CONSULTING

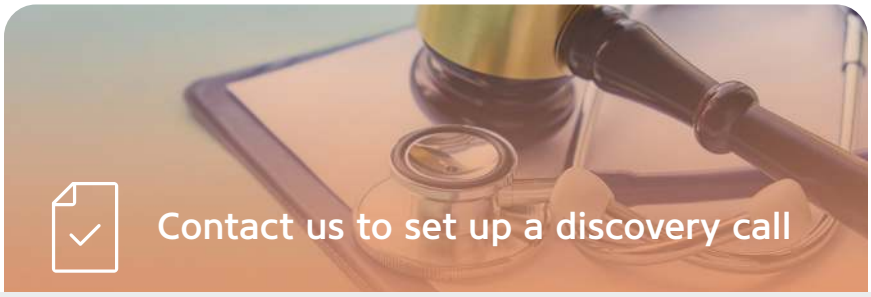
Medical Device Regulatory Affairs Consulting

Lean into our Regulatory Affairs and Compliance Know-How

With the medical device regulatory environment continually evolving, clients depend on our team of experts to provide crucial guidance to expedite time to market.

Failure to comply with regulatory requirements can trigger recalls or delay approvals of new products, resulting in costly mistakes. We guide clients throughout the product life cycle, including defining regulatory strategies, developing regulatory submissions, and assessing the regulatory impact of labeling and design changes.

A key to success for getting your product to market in the US, starts with developing your regulatory strategy. There are many elements under FDA regulations ranging from proper indications for use to labeling, that you may not understand thoroughly, and for which you may seek expert advice.



Our team of experts can prepare custom-tailored regulatory documentation that meets your business objectives, including:

- FDA Presubmission
- FDA 513(g) Request for Information
- FDA 510(k) Premarket Notification
- FDA Premarket Approval (PMA)
- FDA Investigational Device Exemption (IDE)
- CE Technical Documentation and Design Dossiers
- Clinical Evaluation Report (CER)
- Health Canada Licenses
- Good Laboratory Practices (GLP) support documentation
- Other country submissions, as requested

Staff Expertise

- ASQ Certified Quality Auditor
- ASQ Certified Quality Engineer
- ASQ Certified Software Quality Engineer
- ASQ Certified Quality Inspector
- ASQ Certified Quality Technician
- ASQ Certified Manager of Quality/ Organizational Excellence
- Exemplar Global Lead Auditor
- RQAP- Good Laboratory Practicesl

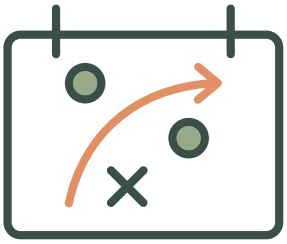
Company Credentials

bsi. ISO 13485 Medical Device Quality Management

certified WBENC WOMEN'S BUSINESS ENTERPRISE

HUB Statewide Historically Underutilized Business Program

Regulatory and Approval Expertise



In order to ensure that your medical device is safe and gets to market on time, it's critical to find a knowledgeable partner who can help you navigate the FDA landscape.

QA Consulting counsels clients who are pursuing FDA approval for their medical devices on a number of key steps to help ensure success.

Specialty areas include:

- Regulatory Strategy
- Pre-Submissions
- 513(g) Requests
- Investigational Device Exemption (IDE)
- 510(k) Premarket Notification Submissions
- Predicate Selection
- De Novo Request
- Premarket Approval (PMA)

Our regulatory consultants have experience across all medical markets to advise you on the appropriate paths to market, including a device's classification and applicable regulations.

We can help you succeed in this process and document a regulatory strategy to consolidate the findings and accurately disseminate your company's plan to key stakeholders such as project team members, board members, and financial investors.

512-328-9404

Contact us today to talk to a regulatory affairs expert!

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