QA CONSULTING

Medical Device Consulting Services

Your Innovation. Our Expertise

QA Consulting is your trusted partner for tailored quality systems, regulatory affairs, and microbiology analysis services throughout the product lifecycle.

From start-ups to multinational corporations, discerning medical device manufacturers of all sizes rely on our real-world knowledge, expert documentation, and mastery of industry protocols and procedures to navigate today's constantly evolving environment.

Whether you require expert consulting services or need to completely outsource your quality or regulatory departments, QA Consulting will tailor pragmatic solutions that ensure your organization exceeds the highest industry standards to help you avoid regulatory roadblocks and guide you along a path to future success.

Lean into quality with medical device systems everyone can trust.

20 YEARS

Celebrating 20 Years of Success

> *"Over the past 20 years, I have carefully cultivated a team of experts for QA Consulting who share integrity and enthusiasm for our work. I have handpicked each member of our staff for his or her diverse experience within our industry, as well as attention to detail. I can say with certainty that our consultants collectively provide unparalleled customer service as well as unique and creative solutions for projects or budgets of any scope or size. At QA Consulting, we are connoisseurs of Quality!"*
>
> Anne Holland
> CEO and Founder

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 Practices

Company Credentials

bsi. ISO 13485 Medical Device Quality Management

certified WBENC WOMEN'S BUSINESS ENTERPRISE

HUB Statewide Historically Underutilized Business Program

Quality Systems

Our team of experts analyzes your needs and objectives to develop pragmatic, disciplined quality systems and strategies. With clear and concise documentation, we prepare clients to pass audits and avoid future roadblocks. QA Consulting can work with your business as your outsourced Quality department or we can work with you to educate or train your team on industry best practices.

We have medical device quality consultants ready to work with you on custom-tailored solutions for:

- Audits
- Design verification and validation
- Complaint Assessments
- Post-production compliance
- Project management
- Quality management system (QMS) development and implementation
- Quality system training
- Risk management
- Process Validation
- Unique device identification (UDI)
- Virtual document control
- Quality Assurance Unit (QAU) for Good Laboratory Practices (GLP) Studies

Regulatory Affairs

We guide clients throughout the product lifecycle, including defining regulatory strategies, developing regulatory submissions, and assessing the regulatory impact of labeling and design changes.

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)
- Post Market Surveillance
- CE Technical Documentation and Design Dossiers
- Clinical Evaluation Report (CER)
- Health Canada Licenses
- Other country submissions, as requested

Microbiology Analysis

Our team can serve as your liaison with a network of supporting laboratories to develop a plan to help you achieve biological safety of your medical device.

We have medical device microbiology consultants ready to work with you on custom-tailored solutions for:

- Biocompatibility assessments
- Sterilization efficacy and validation studies for ethylene oxide (EO), gamma, e-beam, and moist heat (steam) processes
- Biological evaluation reports
- Cleanroom qualification and monitoring
- Cleaning and disinfectant efficacy and validation studies for reusable devices

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