



Medical Device Quality Systems Consulting

Lean into our Quality Systems Know-How

As your medical device consulting and outsourcing partner, QA Consulting is your trusted go-to source for educational information on industry protocols, procedures, and regulatory updates worldwide.

Our team of experts analyzes your needs and objectives to develop pragmatic, disciplined quality systems and strategies.

From startups 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. For smaller medical device companies QA Consulting can serve as your outsourced quality department. For larger enterprises we can work with you on a project basis to supplement your internal team's specific requirements.

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

- ✓ Audits
- ✓ Design verification and validation
- ✓ 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



Contact us to set up a discovery call

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

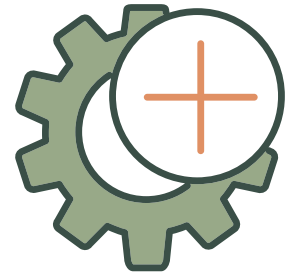




Quality Management Systems Expertise

A well thought out and implemented Quality Management System (QMS) provides the overarching structure for operating your medical device business in an efficient and compliant way.

QA Consulting has worked with more than 50 medical device manufacturers to write and implement Standard Operating Procedures (SOPs) for their quality management systems.



We take great pride in that each of these companies has successfully completed FDA inspections and notified body audits without the issuance of a single Warning Letter or Major Nonconformance.

The foundation of a successful Quality Management System is a series of thoughtfully developed SOPs that set the stage for how a company should operate. Our project managers will approach your SOP generation by dividing the SOPs across multiple phases in an order that best fits your company's development process.



Medical Device Auditing Expertise

Audits provide necessary checks and balances on quality systems, confirm that suppliers meet expectations, and enable manufacturers to maintain their ISO 13485 certification.

Our team of qualified experts has conducted more than 300 audits. We can help you conduct supplier and internal audits as well as prepare your team for a notified body audit.



Specialty areas include:

- ✓ Internal Audits
- ✓ Supplier Audits
- ✓ Product and Process Audits
- ✓ Mock Audits

512-328-9404

Contact us today to talk to a quality systems expert!



QA CONSULTING

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