



Elevating MedTech Excellence through Quality and Compliance

In the dynamic world of MedTech industries, ensuring your products meet the highest standards and comply with ever-evolving regulations is paramount. At qointa, we specialize in providing comprehensive Quality and Regulatory Support services, designed to help you navigate complex regulatory landscapes with ease and maintain uncompromising quality in your operations.

Our Comprehensive Services



Pre-Market Submissions - 510(k), CE Marking

We assist in preparing and submitting pre-market documentation, such as 510(k) submissions and CE Marking, to gain regulatory approval for your medical devices.



QMS Implementation (QSR / ISO)

Our experts guide you in implementing Quality Management Systems (QMS) that align with Quality System Regulations (QSR) and ISO standards to ensure consistent quality.



DHF Gap Analysis

We perform thorough Design History File (DHF) gap analysis to ensure compliance with documentation requirements, facilitating smoother product development and submissions.



CAPA (Corrective and Preventive Actions)

We help you identify, document, and manage Corrective and Preventive Actions to enhance product quality and prevent future issues.



Supplier Engineering

Ensure that your suppliers meet the highest quality and regulatory standards through our supplier engineering services.



Audits and Assessment

We conduct audits and assessments covering your Quality Management System (QMS), suppliers, and training to identify areas for improvement and ensure **compliance**.



Compliance to IEC 60601-1

Our experts perform gap analysis, compliance testing, and certifications to ensure that your medical devices meet the requirements of IEC 60601-1.



Design Verification and Validation Services

We offer comprehensive verification and validation services, including system and subsystem testing, requirements management, reliability testing, compliance testing, and certifications.



Compliance to IEC 62304 (Software Lifecycle Management for MD)

We assist in adhering to the standards outlined in IEC 62304 for the software lifecycle management of medical devices.



Risk Management (Compliance to ISO 14971)

We provide comprehensive risk management services, including hazard analysis, FMECA, and FTA, to comply with ISO 14971 standards.



Computer Systems and Software Validation based on FDA Regulations

We help you validate computer systems and software according to FDA regulations to ensure data integrity and security.



FDA 21 CFR Part 11 ER/ES Consulting

Our consulting services cover gap analysis, risk analysis, and remediation to comply with FDA 21 CFR Part 11 Electronic Records and Electronic Signatures requirements.



Data Privacy & Protection (US/EU)

We assist in ensuring compliance with data privacy and protection regulations in both the US and the EU.



Development of SOPs and Process Guidelines

We help you develop Standard Operating Procedures (SOPs) and process guidelines that are in line with regulatory requirements and industry best practices.

Are you Regulatory Compliant?

Are you searching for expert guidance to ensure your MedTech products meet the highest quality standards and navigate the complex regulatory landscape seamlessly?

Need support in preparing and submitting pre-market documentation, such as 510(k) submissions and CE Marking, to gain regulatory approval for your medical devices?

Looking to enhance your Quality Management System (QMS) through QSR and ISO implementation to achieve consistent quality and compliance?

Interested in rigorous risk management and safety assessments for your medical devices to comply with ISO 14971 standards and ensure patient safety?

Want to ensure your computer systems and software adhere to FDA regulations and data privacy standards to protect patient information and ensure regulatory compliance?

Why Choose qointa?

01 Regulatory Mastery

We excel in understanding and navigating complex regulatory requirements, ensuring compliance and product approval.

02 Quality Excellence

qointa is committed to helping you maintain the highest standards of quality throughout your operations.

03 Global Expertise

Our team has extensive experience in dealing with regulatory standards and compliance across the globe.

04 Customized Solutions

We tailor our services to your specific needs, ensuring a personalized and effective approach.

05 Holistic Approach

Our services cover every aspect of quality and regulatory support, offering a one-stop solution for your needs.

**“Safeguarding Your Data,
Elevating Integrity to
Excellence.”**



qointa's Quality and Regulatory Support services are your trusted partners in achieving and maintaining excellence in the MedTech industry. Let us help you navigate the complex landscape of regulations and uphold the highest standards of quality in your operations.

Elevate your quality and regulatory compliance with qointa.

Contact us today to explore how our services can empower your Life Science journey.



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