



From Concept to Compliance-Ready Market Launch

Revolutionizing Healthcare Through Innovative Software Solutions

In today's digital age, software is a driving force in the transformation of medical devices and healthcare solutions. At qointa, we are at the forefront of this revolution, specializing in the development of Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD). Our mission is to create regulatory-compliant, innovative, user-friendly, and safe software solutions that propel the healthcare industry into the future.

- Seeking full lifecycle software development services to bring your medical device concept to reality, from design to deployment and beyond?
- Need support in designing regulatory-compliant software and enhancing your cybersecurity measures to protect sensitive patient data?
- Interested in ensuring the reliability and safety of your medical device software through rigorous verification and validation services?

Our Comprehensive Services

Full Lifecycle Software Development



We provide end-to-end software development services, from conceptualization and design to development, testing, and deployment. Our team ensures that your software solution is tailored to your unique needs and objectives.

Regulatory Compliant Software Design



Regulatory compliance is a non-negotiable aspect of medical device software. qointa's experts are well-versed in global regulatory requirements and design software that meets and exceeds these standards, ensuring safety and effectiveness.

Risk Management and Cybersecurity Solutions



We understand the critical importance of cybersecurity in healthcare. qointa incorporates robust risk management and cybersecurity solutions to protect sensitive patient data and ensure the integrity of your software.

At qointa, we transform your ideas into safe, compliant, and market-ready software, providing end-to-end support across the entire product lifecycle. Our solutions align with US FDA and EU MDR/IVDR regulations, ensuring your product is FDA-cleared, CE-marked, and ready to reach the market quickly and efficiently.

Your intellectual property always stays with you. When needed, we provide a seamless transfer of all documentation, empowering your team to take ownership and maintain your product confidently.

Your Gateway to Digital Healthcare Excellence

Verification and Validation Services



Rigorous testing and validation are essential to guarantee that your software performs as intended. Our verification and validation services ensure that your software is reliable, accurate, and safe for use in medical applications.

User Interface and User Experience Optimization



User-friendliness is paramount in the healthcare industry. qointa focuses on optimizing user interfaces and user experiences to ensure that healthcare professionals and patients can use your software effortlessly and effectively.

Post-Market Support and Updates



The journey doesn't end with deployment. We offer post-market support and updates to keep your software up-to-date, secure, and aligned with evolving industry standards.

Developing medical device software – whether Software as a Medical Device (SaMD) or Software in a Medical Device (SiMD) – is a complex process that requires specialized expertise, cutting-edge technology, and strict adherence to regulatory standards. Mistakes can lead to costly delays, compliance issues, or compromised patient safety.

This is where outsourcing becomes critical. Partnering with an experienced team like quinta ensures that your product is in capable hands, offering:

- **Regulatory Expertise:** Seamless navigation of FDA, EU MDR/IVDR, CE, and ISO requirements.
- **Cost and Time Savings:** No need to build and maintain in-house teams or infrastructure.
- **Focused Innovation:** Free your internal teams to focus on core business objectives while we handle the complexities of development and compliance.

Our Expertise at Every Stage: A Comprehensive Lifecycle Approach

From initial concept to post-market updates, our services are designed to meet the unique challenges of medical device software development.

1. PLANNING & STRATEGY

- Idea Validation
- Feasibility Studies
- Regulatory Pathway Analysis

2. REQUIREMENTS & DESIGN

- Functional & Technical Specifications
- Risk Assessment (ISO 14971)
- UI/UX Prototyping – Visualize and refine your product before development
- User-Centric Design: Enhance patient and healthcare provider experience

3. DEVELOPMENT

- Agile Software Development tailored to SaMD and SiMD needs
- Integration with Hardware Systems
- Secure Coding Practices

4. VERIFICATION & VALIDATION

- Testing & Defect Resolution
- Compliance Documentation (FDA 21 CFR Part 11, IEC 62304)
- End-User Testing

5. LAUNCH & POST-LAUNCH SUPPORT

- Regulatory Submission Support
- Real-World Evidence (RWE) Generation (to leverage data for continuous improvement)
- Maintenance, Updates, and Enhancements
- Ongoing compliance with evolving regulations

Why Choose quinta?

01 Unmatched Expertise

With over 50 years of combined experience in digital and regulatory solutions for life sciences, we bring deep technical expertise and industry insights.

02 Compliance-First Approach

We ensure strict adherence to global standards, including FDA, EU MDR, and ISO guidelines, to keep your product market-ready and audit-proof.

03 Comprehensive Lifecycle Support

From strategy and development to post-launch maintenance, we provide end-to-end services tailored to your needs.

04 Tailored Solutions

Whether you're a startup or an established enterprise, our customized solutions are designed to address your unique challenges.

05 Innovation with Safety

We blend cutting-edge technology with rigorous quality control to deliver software that is both innovative and compliant.

quinta's Medical Device Software Development is your gateway to transformative healthcare solutions. Our expertise in SaMD and SiMD ensures that your software not only meets regulatory requirements but also sets new standards for innovation and usability.

Let's Build the Future Together

Whether you're a startup or an established enterprise, we're here to bring your vision to life while ensuring the highest standards of safety, efficacy, and compliance.

Empower your healthcare journey with quinta.

Contact us today to explore how our services can elevate your medical devices.



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