



Software for your medical device

Successfully navigate the complex regulatory landscape with Firefinch

Summary

Software plays a pivotal role in delivering innovative solutions for diagnostics, treatment, and management to improve patient care and outcomes. But developing software for a medical device requires stringent adherence to global regulatory standards and ensuring compliance across various frameworks.

Your collaborative partner in compliance-driven innovation

Firefinch has extensive experience in delivering software solutions that meet the highest standards of safety, effectiveness, and performance to ensure you rapidly gain regulatory approval. We can provide you with the expertise to develop your medical device software, guiding you from concept to commercial reality with strategic advice and support.

EXPERIENCED

We can work under an existing ISO 13485 QMS, or help guide you with setting up and developing the framework if needed.

KNOWLEDGEABLE

We know how to write software that is compliant with IEC 62304 and can integrate with systems using HL7 protocols, including FHIR.

AGILE

We are proficient at using the guidance in AAMI TIR:45 to develop software in an Agile manner.

FLEXIBLE

We are experienced designing software that allows devices to comply with 21 CFR Part 11 – or adding 21 CFR Part 11 compliance features to existing instruments.

Capabilities



DESKTOP DEVICE
CONTROL SYSTEMS



CLOUD-BASED
APPLICATIONS



ALGORITHMS &
SIGNAL PROCESSING



DATA ANALYSIS



MACHINE LEARNING & AI

Our expertise in medical software development means we deliver robust, agile, and secure solutions tailored to your needs and requirements. Our track record of success in meeting regulatory standards and delivering high-quality products makes us the ideal partner to navigate the complex landscape of medical software development.

We know just what it takes to develop successful software

AAMI TIR45 - AGILE PRACTICES

We use Agile methodologies aligned with AAMI TIR45 to adapt to our clients' evolving needs. Our iterative approach enables rapid prototyping, testing, and deployment, allowing us to respond efficiently to regulatory changes, user feedback, and technological advancements.

HL7 AND FHIR PROTOCOLS

We know how to integrate HL7 and FHIR protocols to enable seamless interoperability with healthcare systems. This ensures that your software solutions are capable of securely exchanging data across different healthcare applications, supporting the integration of electronic health records (EHRs) and improving patient care outcomes.

ISO 13485 COMPLIANCE

We are experienced at working under ISO 13485, the international standard for quality management systems specific to medical devices. This ensures that your software is designed, developed, and maintained with the highest level of quality assurance.

IEC 62304 - MEDICAL DEVICE SOFTWARE LIFECYCLE PROCESSES

Following a structured software development lifecycle in line with IEC 62304, we integrate risk management, verification, and validation to ensure your software meets safety and performance standards, effectively mitigating risks throughout development.

21 CFR PART 11 COMPLIANCE


Our expertise extends to developing software that complies with 21 CFR Part 11, the FDA's regulations on electronic records and signatures. This allows for robust authentication, audit trails, and data integrity measures, making them suitable for use in regulated healthcare environments.


About Firefinch

With Firefinch you can access a range of specialist skills from across the life sciences, engineering, and manufacturing to help you reach commercial success as soon as possible. Our team brings together scientific expertise, software development skills, and extensive product development experience to tackle the challenges of turning ideas into commercial success. We provide the technical expertise to meet product requirements and act as a strategic partner, offering guidance and insight every step of the way.

Get in touch

Contact us today to discuss how we can accelerate your software development while ensuring full compliance with global regulatory requirements.

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 Firefinch Software