GlobalLogic Solutions: Medical Device Software Development

Driving Exceptional Patient Experiences with SaMD

Introduction

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Our services enable these organizations to get products to market faster and transform healthcare through technology and innovation.

In this highly regulated industry, it is essential to work with a partner whose software engineering skills come intertwined with a deep quality culture and a strong working knowledge of the governing ISO/IEC standards.

From embedded systems and software as a medical device (SaMD) to clinical study platforms, internet of medical things (IoMT), and telehealth, GlobalLogic has helped the world's leading medical technology, CROs, and diagnostics organizations design, develop, and deliver world-class digital patient experiences for over 20 years.

In this solution guide, we explore the key areas where GlobalLogic can help you develop medical device/IVD software, digital health platforms, healthcare information exchanges, IoMT and smart healthcare systems that facilitate telehealth, and health data intelligence and diagnostics (HDID).

At GlobalLogic, we believe that when you create high-quality medical devices that are easy to use, it increases your business value as well as your value to your clients.

We've learned that whenever you can create patient value in the marketplace, good things will follow.

Given the technical sophistication of today's environments, the best way to achieve that end is to increase your creation potential and innovation by working with a knowledgeable, scalable, and trusted technology partner.

Medical Devices and Software Development

Explore what is driving rapid growth in the medical devices industry and see how SaMD is driving new revenue for clients.

Medical devices and applications have become a fundamental and critical part of how medical treatment is delivered.

They provide vastly improved ways for clinicians to treat, diagnose, rehabilitate, and even prevent illnesses in a safe, secure, and effective way. Recent exponential growth in the medical devices industry, including software as a medical device (SaMD), is being driven largely by:

The inherent value of engaging directly with patients to play an active role in their disease management.

The increasing computing power and high-quality visual presentation capability embedded in mobile phones. With ubiquitous communications capabilities, medical device software architects are able to partition the functionality of medical device systems and repartition key product attributes to the mobile phone, taking advantage of more capability and lower cost of goods sold (COGS).

The significant rise in data captured, communicated, and made available for cloud computing and analysis, along with the significant reduction in the actual cost of cloud computing. This is fueling a major buildout of data lakes and HCP analysis capability.

How GlobalLogic Can Help

As a fully ISO 13485–certified partner, GlobalLogic can help you expedite the development of embedded software and SaMD applications.

We maintain a virtual "innovation lab" across our global engineering centers to create compelling use cases, develop meaningful prototypes, and participate in activities that have a direct impact on your product roadmap.

We're ready to hit the ground running with:

- Strong embedded skills in using real-time operating systems
- Extensive experience using Linux as an embedded system
- Fluency with the languages and designs associated with these systems, like C++ and C
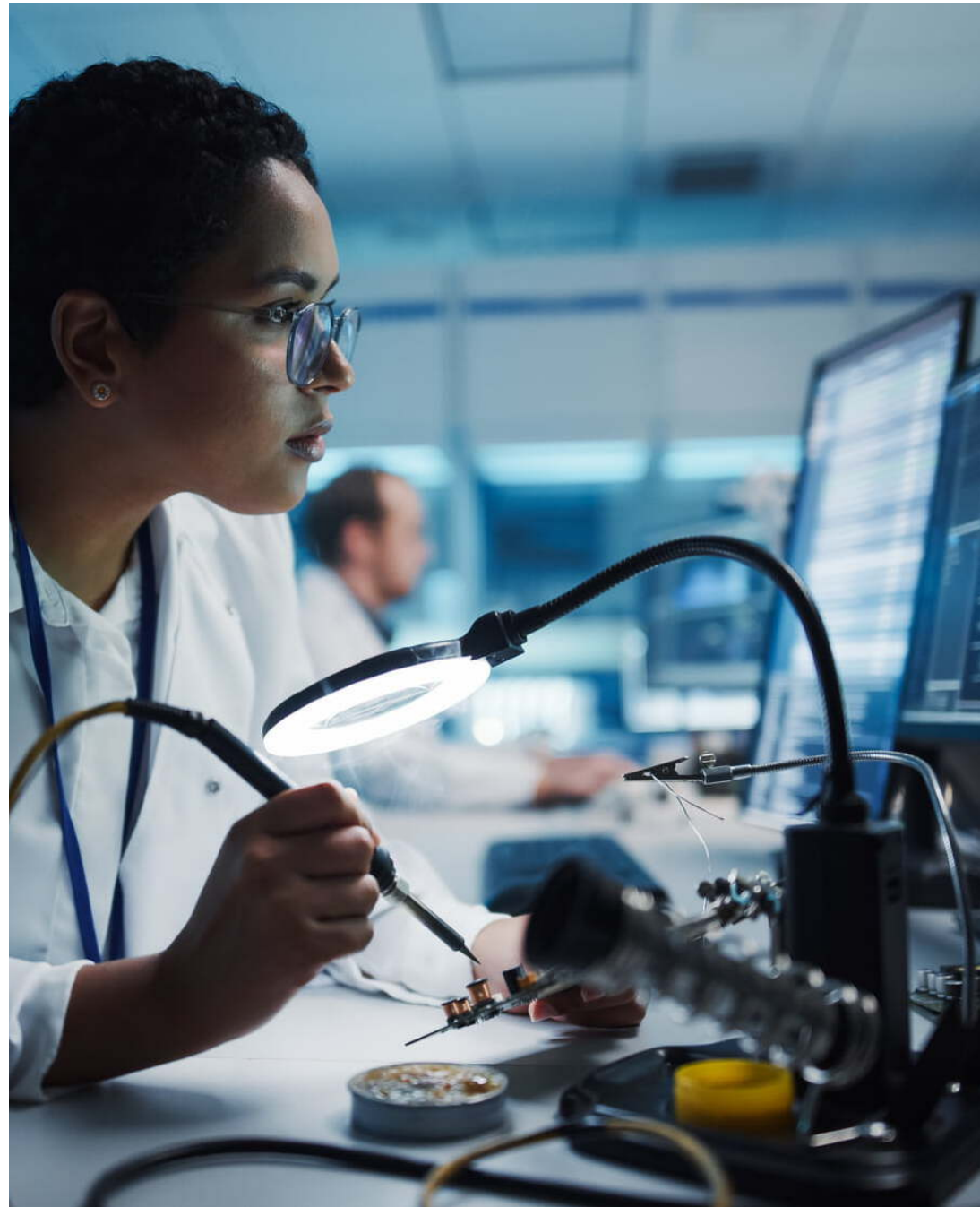
Learn more about our Healthcare & Life Sciences services

GlobalLogic has the extensive experience, insights, and standards you need to navigate the rigid compliance requirements surrounding SaMD systems.

Our products are regulated under ISO and IEC standards that include:

- Patient engagement applications on mobile devices that are associated with diagnosis or therapy.
- Patient and healthcare clinician applications deployed on healthcare desktops, networks and clouds used for making patient diagnosis and treatment decisions.

GlobalLogic helps to integrate mobile devices, mobile apps, and tethering communications while enabling data analytics capabilities for diagnostics and treatment.

Software as a Medical Device (SaMD)

SaMD is becoming more prevalent in healthcare as artificial intelligence (AI) and machine learning (ML) technologies are used for decision-making processes.

SaMD is a very strict designation by regulators covering all software systems established to provide diagnostic care or therapy — for example, a mobile app that helps diabetics manage their insulin dosing.

Unlike medical devices, SaMD apps do not run on controlled medical instruments. They include any applications residing on these new emerging non-medical device platforms involving therapy or diagnostics.

For instance, the mobile phone medical device apps that integrate seamlessly with their medical device counterparts are defined as SaMD applications and are regulated as such.

Given that, clinicians do not want to be tethered to an instrument to analyze and diagnose patients, and the use of SaMD applications allows them this freedom.

How is your company currently using AI and/or ML? (Choose all that apply)

- [ ] Internally in our back office systems
- [ ] Internally in public or patient-facing systems
- [ ] In therapeutic and diagnostic applications or products
- [ ] We are not yet using AI/ML but are exploring the possibilities
- [ ] We are not interested in incorporating AI/ML in our business

Post answer

Our Key Differentiators

We excel at helping healthcare organizations create world–class digital customer experiences and transform their business operations.

Deep Medical Expertise

- 20+ years of experience developing regulated FDA (I, II & III products) with FDA clearance and CE mark
- 2300+ engineers dedicated to healthcare and life sciences
- 300+ new products
- ISO 13485 certified QMS, IEC 62304 compliant SDLC

Processes for Healthcare

- Delivery processes tailored to healthcare domain
- Working within our client's QMS or using GlobalLogic's 13485 compliance QMS
- Setting up internal and external audit processes
- Building policies on security and data privacy
- Establishing healthcare and ISO/IEC standards training programs for staff assigned to these projects

Innovative Technologies

- Infrastructure-, platform-, or software-as-a-service (IaaS, PaaS, SaaS) implementations using public, private, and hybrid deployment models
- Cross-platform development
- AI/ML, big data
- Microservices architecture, DevOps, cloud operations, and management tools
- Embedded systems, Bluetooth Low Energy (BLE), Wi-Fi, near-field communication (NFC) integration

About GlobalLogic

With more than 20 years of experience in regulated software product development and engineering services, GlobalLogic helps some of the world's leading Medical Technology, Medical Devices, Pharma, and Life Sciences organizations create world–class digital patient experiences, accelerate new product development, and capture new revenue streams.

GlobalLogic®
A Hitachi Group Company

20+ years industry experience

2300+ industry-dedicated engineers

300+ new products

90+ clients

GlobalLogic is a trusted partner in the fields of medical devices, medical technology, clinical research, and diagnostics.

We develop Class I, II, and III products in accordance with ISO 13485 certified QMS and IEC 62304 compliant SDLC.

Why choose GlobalLogic as your software engineering partner?

- Our deep working knowledge of ISO governing standards enables us to work with many different companies' QMS and SDLC.
- Our experience in using various tools, software languages, cloud environments, and infrastructure to integrate and collaborate with your in-house engineering team seamlessly.
- Our experience in building, designing, implementing, and testing systems per agreed-upon product definitions and specifications.

To learn more, or to speak with one of our experts, please reach out to info@globallogic.com.

We are on a two-decade-young journey and we're proud of our growth and the milestones we have achieved. A startup to a Hitachi group company, our product engineering story is unique. Thanks to our people who have been our companions and growth drivers in this amazing journey.

'We are GlobalLogic' is a spectacular showcase of what we do, what we represent, and our capabilities as a global leader in product engineering services.

Learn More: Visit Our Website

Thank you for reading

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