

# Medical Device Software Development (SaMD) Case Studies

GlobalLogic Partnerships That Transform Patient Care Services





Partnerships That Create World-Class Digital Patient Experiences The world's leading MedTech, Med Devices, CROs, and In Vitro Diagnostics organizations are continuously seeking new ways to improve the quality and increase the value of the care they bring to their patients.

They are tapping into the power of digital technologies to drive down costs, increase access to care delivery, and improve medical care.

Creating a user-friendly mobile app that communicates with a patient's medical therapy device can increase patient engagement, enabling much better patient performance, improving patient satisfaction, and helping the patient complete their therapy faster.

And embedding data management software and enabling connectivity for medical devices can make data more readily and rapidly available to be analyzed, creating opportunities for product innovation. If your organization is embarking on any new digital engineering initiative or looking to adopt cutting-edge modern technologies in a strictly regulated environment, GlobalLogic can help.

GlobalLogic is a pioneer in developing solutions ranging from embedded medical device software to Software as Medical Devices (SaMD) and other patient therapy devices, as well as connected health systems and digital healthcare platforms.

Here are some success stories of organizations that partnered with GlobalLogic to create enhanced patient value that drives business outcomes.

#### Let's Work Together

Searching for a new engineering partner? Let's see how we can help. <u>Click here to reach out to us.</u>



# Sound-Processing Software Development

The improvements made in the sound-processing systems enabled clinicians to be more engaged to tune or adjust the various settings to personalize device performance for each individual patient.

#### **Client Scenario**

An Australia-based medical device company that designs, manufactures, and supplies cochlear implants to improve hearing for those with severe to profound deafness faced a business dilemma.

They needed to refresh their legacy sound-processing software, which clinicians used to tune each device and personalize it for each patient.

With limited access to software engineering talent, and their staff dedicated to maintaining the current software, there was little opportunity to develop new features and enhancements that would increase value for their end customers and implant recipients.

# **Our Approach**

Stepping in as a strategic partner, the GlobalLogic engineering team, with 20+ years of experience in medical device software development, worked in tandem with the client's software engineering team to review their issues list and improve the quality of the existing software system, all while providing assurance that the software developed adhered to compliance and other regulatory standards. Building on this success, the client further requested that GlobalLogic develop, verify, and validate the next generation of their flagship sound-processing software product as per ISO 13485 / ISO 62304 / ISO 14971, CFR 21, and other regulatory standards.

To attain this approval, medical products need to be developed and tested in accordance with the harmonized standards that govern medical device software, namely ISO 13485, ISO 14971, IEC 62304, and IEC 62366.

#### Benefits

Partnering with GlobalLogic helped the client resolve backlogged critical software issues rapidly and improved their ability to bring their flagship product to market. With a systematic knowledge transfer approach, the client approached a steady state level within three months.

Now clinicians have updated, modernized software released with each new sound processor/implant, helping create improved clinician satisfaction and maintaining brand loyalty with their clinician base.



# Development of a Wearable Application for Health Monitoring

Blending client marketing and clinical knowledge with GlobalLogic's expertise drives products in emerging technology platforms. GlobalLogic can apply experience gained in a commercial or communications vertical to the medical vertical, improving the client's ability to have a strong first-generation release.



#### **Client Scenario**

A multinational manufacturer of medical devices used in interventional medical specialties was developing a new SaMD product. It would be used to monitor patient health, collecting biometric data and running complex algorithms to help study the patient's response to closed-loop therapy.

To make it easier and more natural for patients to use, the SaMD would be distributed as a smartwatch application. The challenge was that the manufacturer had limited experience working within smartwatch platforms.

# **Our Approach**

The client partnered with GlobalLogic to leverage the latter's experience in developing consumer-facing mobile apps across multiple industries as well as in identifying elements that contribute to app and wearable success.

GlobalLogic tapped its deep technical knowledge to assess platforms against the client's functional and nonfunctional requirements and established a wearable strategy leveraging iOS and Samsung operating systems. GlobalLogic then developed the wearable and mobile applications and a highly extensible framework for deploying new applications.

#### Benefits

The resulting software application is flexible enough to allow the client to amend biometric data collection without having to redeploy new sets of applications to study participants.

This saves critical time and resources and helps reduce the impact of such changes on study participants.

By using popular mobile platforms, the client indirectly encouraged patients to actively participate in their treatment, avoiding the potential stigma of traditional devices.

The solution GlobalLogic developed also allows for use with different wearables, in each case collecting data and transmitting it to a data lake for processing.

# 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<sup>®</sup> A Hitachi Group Company

20+ years industry experience 2300+ industry-dedicated engineers  $\mathbf{300}$ new products 90 +clients

To learn more or 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.

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