

REVOLUTIONIZING HEALTHCARE THROUGH CONNECTED MEDICAL DEVICES & SOFTWARE AS A MEDICAL DEVICE



Transforming Healthcare, One Innovation at a Time

Connected Medical Devices and Software as a Medical Device (SaMD) are redefining the future of healthcare. Leveraging real-time data and advanced analytics, these cutting-edge solutions enable personalized care, predictive insights, and faster, improved outcomes for patients worldwide.

At Infosys, we bring healthcare providers and MedTech organizations the expertise to design, develop, and deploy innovative solutions. Together with Kaleidoscope Innovation, we combine global insights with deep technical and regulatory expertise to help clients deliver life-changing products while ensuring safety and compliance.



Our Key Offerings



Product Design and Development

- Comprehensive system engineering for robust, scalable devices
- Human Factors Engineering for user-friendly, safe designs
- Rapid prototyping with our in-house labs
- Expertise across mechanical, electrical, and biomedical engineering



Advanced Software Development

- Compliant with IEC 62304 and international guidelines
- User-centric mobile and web applications
- Secure cloud hosted analytics and insights
- Trusted AI/ML integration aligned with FDA's GMLP



Quality & Regulatory Assurance

- FDA, EMA, and global regulatory strategy support
- Regulatory submission support for FDA 510(k), PMA, CE Marking and ROW regions
- Risk management (ISO 14971) and Quality Management Systems (ISO 13485 and FDA 21 CFR Part 820) solutions.



Connectivity & Data Management

- Seamless IoT integration for connected care
- Secure cloud data management platforms
- EMR and hospital system integrations



Verification & Validation (V&V)

- Usability, system, software, and hardware V&V
- AI model fairness and bias testing
- Comprehensive clinical validation – Study Design, execution and regulatory submission



Cybersecurity & Compliance

- HIPAA, GDPR, and global privacy compliance
- Threat modelling, vulnerability assessments, and incident management



Post-Market Support

- Remote monitoring and predictive maintenance
- Continuous AI model validation and training
- Regulatory compliance monitoring and auditing

Why Choose Infosys?

Proven Experience

- Over 15 years of collaboration with healthcare leaders, including 8 of the top 10 medical device manufacturers globally.
- Expertise across Class I, II, and III medical devices across therapeutic areas.
- Comprehensive experience in clinical trial execution, regulatory submissions, and end-to-end product lifecycle management.

Regulatory and Compliance Excellence

- Proven track record of successful FDA 510(k), PMA, CE Marking, and global region-specific submissions.
- ISO 13485 certified Medical Device QMS, and extensive experience with ISO 14971, IEC 62304 and IEC 62366 compliance
- Strong proficiency in designing HIPAA and GDPR compliant solutions.

Robust Technical Expertise

- A globally positioned workforce with specialized knowledge in Medical Device Engineering, IoT, software platforms, wireless connectivity, and AI/ML solutions.
- Agile and DevSecOps practices to deliver secured and high-quality solutions at speed.
- Dedicated teams for cybersecurity, ensuring robust threat modelling, penetration testing, and incident management frameworks.

Human Centric and Innovation-Focused Approach

- End-to-end product design and development services, from early concept ideation to rapid prototyping through in-house labs in the USA and India.
- Human Factors Engineering expertise to design healthcare products that are safe, intuitive, and user-friendly.
- Powered by a dedicated team of SMEs advancing solution delivery across various therapeutic domains.

Global Partnerships and Alliances

- Collaborations with leading hospitals, medical institutions, and research organizations to shape patient outcomes.
- Strong alliances with technology leaders like AWS, Microsoft, Google, IBM, and PTC to build scalable, secure, and innovative solutions.
- Partnerships with testing and certification laboratories to accelerate validation and compliance certifications.

Commitment to Transformative Innovation

- Solutions infused with Infosys' innovation-driven ethos — Infosys DevSecOps Platform, and Clinical Trial Solutions to deliver quality solutions at speed.
- Accelerators like Infosys iSAMD, Infosys Automation Framework and Infosys Responsible AI Suite that empower MedTech organizations to scale rapidly and responsibly.



Success Stories



Remote Patient Monitoring for Heart Failure Patients

We enabled real-time monitoring through BLE enabled devices, AI-powered insights, and seamless dashboards for patients and doctors. This innovative solution ensured timely interventions and improved patient outcomes.



Diabetes Lifestyle Management Platform

Partnered with a diabetes management company to create mobile apps, a cloud-based platform, and a web portal, empowering patients to manage their health with expert coaching support.



Regulatory Support for Class II SaMD

Our team provided comprehensive regulatory support, from developing global strategy to FDA 510(k) submission, for SaMD on cloud that delivers insights based on ultrasound images.



Cloud-Based Radiation Dose Management

We transformed a radiology major's on-premises dose management system to multi-tenant cloud-based system, enabling faster, efficient onboarding of customers and reducing the cost to support on ongoing basis.



Multitenant Remote Monitoring for Biopsy Tissue Processors

Developed a scalable platform for lab technicians to monitor samples in real-time and service engineers to monitor, diagnose, and maintain devices in real-time, improving diagnostics and upkeep efficiencies.

For more information, contact askus@infosys.com

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Navigate your next

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