MEDICAL DEVICES ENGINEERING

Infosys
cobalt

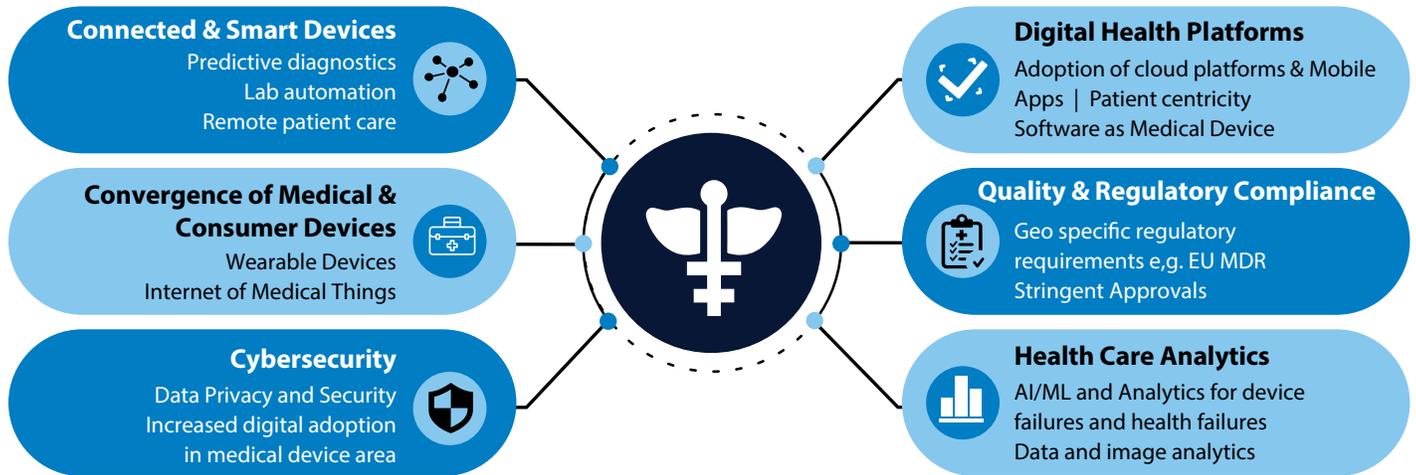Kaleidoscope® Innovation
an Infosys company
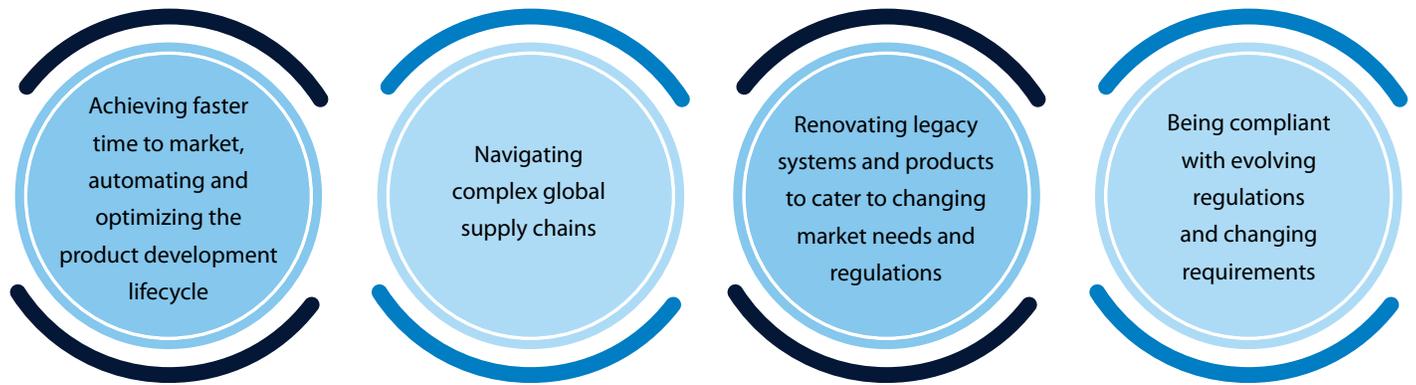
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Navigate your next

Overview, Trends and Challenges

The Life Sciences industry is undergoing a multi-faceted transformation due to continuous advancements in the hyper-personalization of medical procedures and treatments, new generation manufacturing methods, connected operations and increased use of advanced technologies like artificial intelligence (AI) and machine learning (ML).

Life Science and Digital Health Industry Trends

Connected & Smart Devices
Predictive diagnostics
Lab automation
Remote patient care

Convergence of Medical & Consumer Devices
Wearable Devices
Internet of Medical Things

Cybersecurity
Data Privacy and Security
Increased digital adoption
in medical device area

Digital Health Platforms
Adoption of cloud platforms & Mobile Apps | Patient centricity
Software as Medical Device

Quality & Regulatory Compliance
Geo specific regulatory requirements e,g. EU MDR
Stringent Approvals

Health Care Analytics
AI/ML and Analytics for device failures and health failures
Data and image analytics

Some of the major challenges for this industry are

Achieving faster time to market, automating and optimizing the product development lifecycle

Navigating complex global supply chains

Renovating legacy systems and products to cater to changing market needs and regulations

Being compliant with evolving regulations and changing requirements

Further, the COVID-19 pandemic added new challenges to the industry. It prompted new equipment with user-friendly features for patients and doctors, remote monitoring solutions with integrated and interconnected data management solutions for patient care, remote monitoring of devices and laboratory equi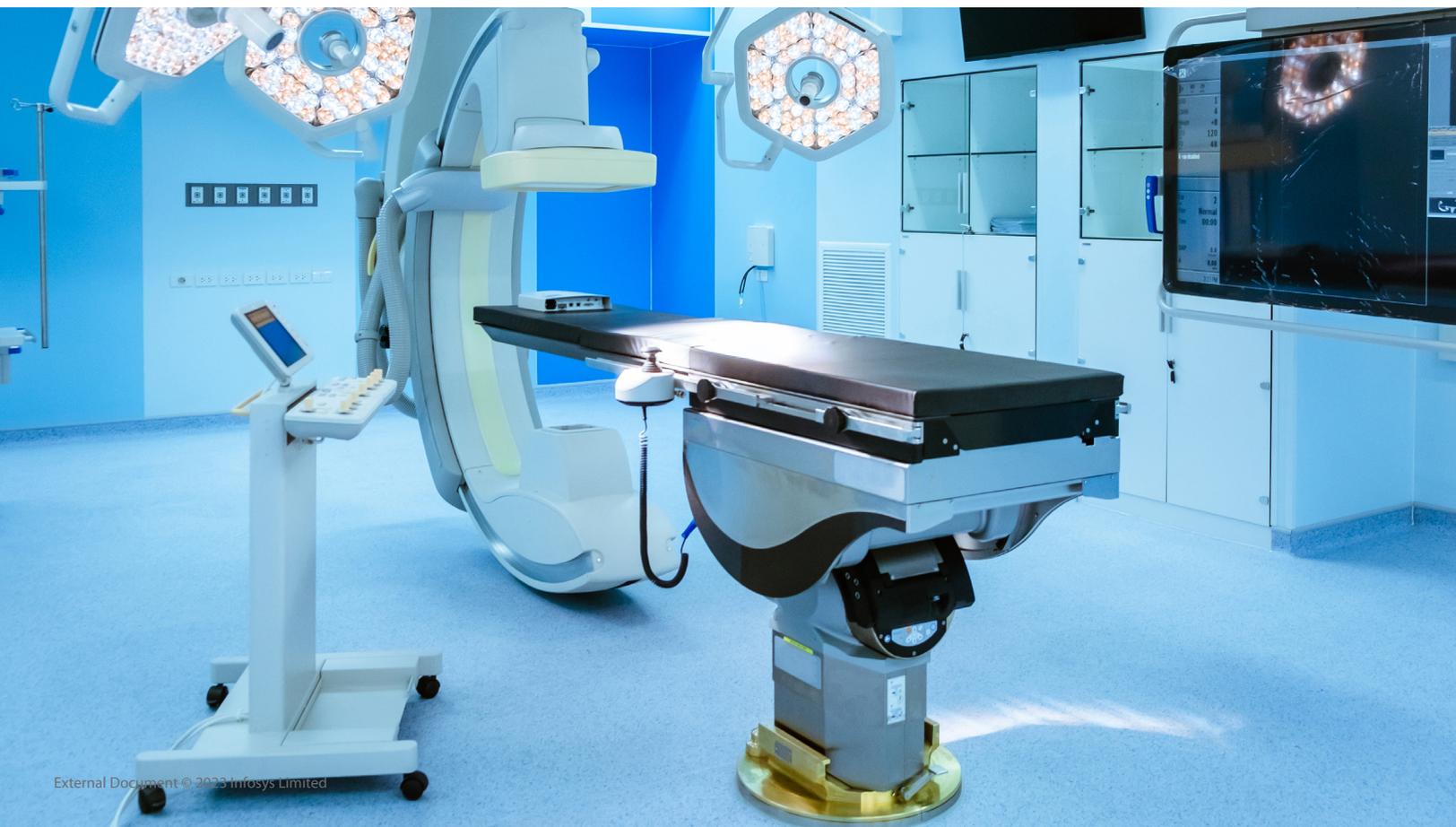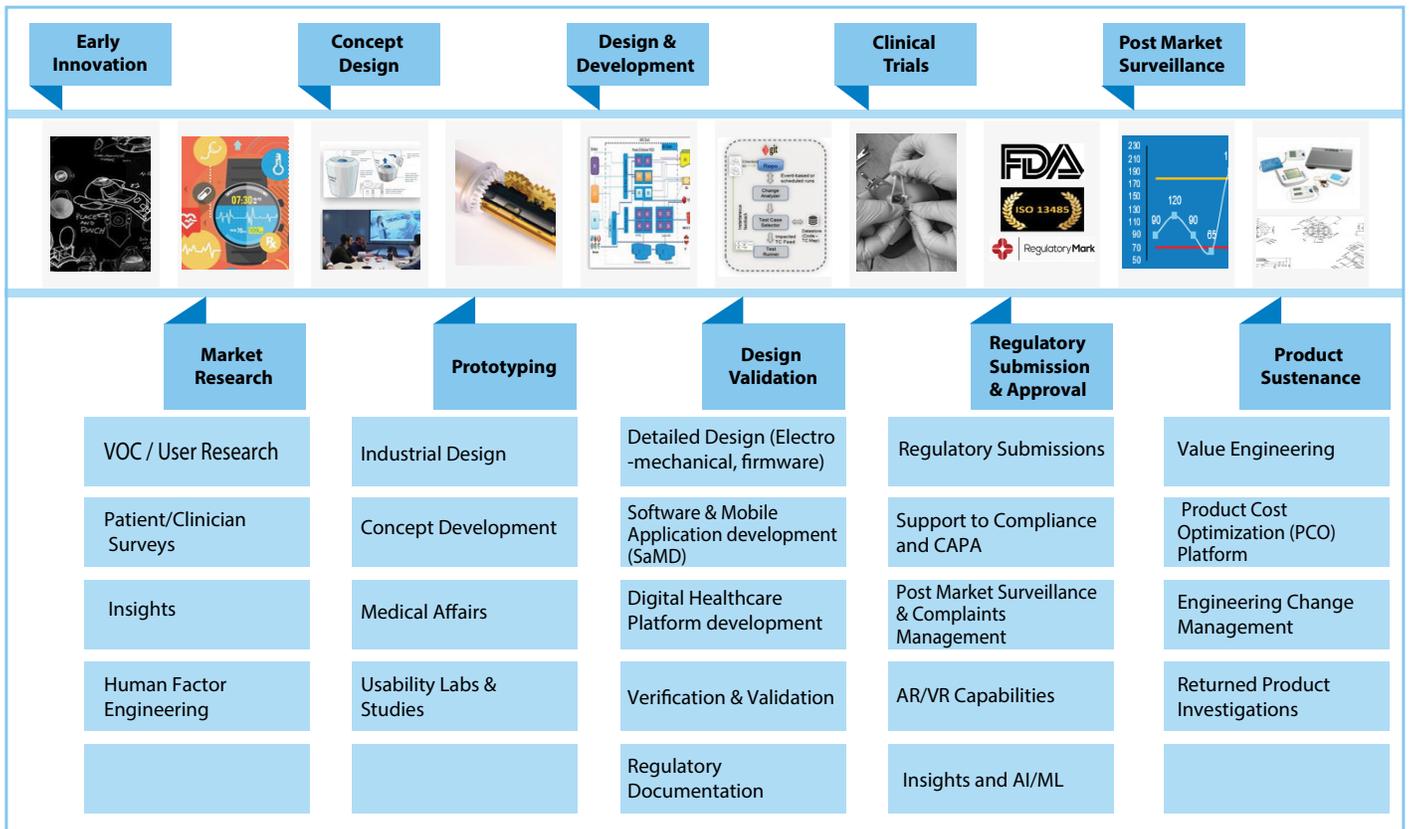pment for higher up-time and predictive maintenance, and cost-efficient equipment owing to huge demand. Such advances need to be made quickly, necessitating faster product development.

With deep expertise and experience in the Life Sciences domain, Infosys Engineering Services understands these challenges and endeavors to Navigate the Next for our customers.
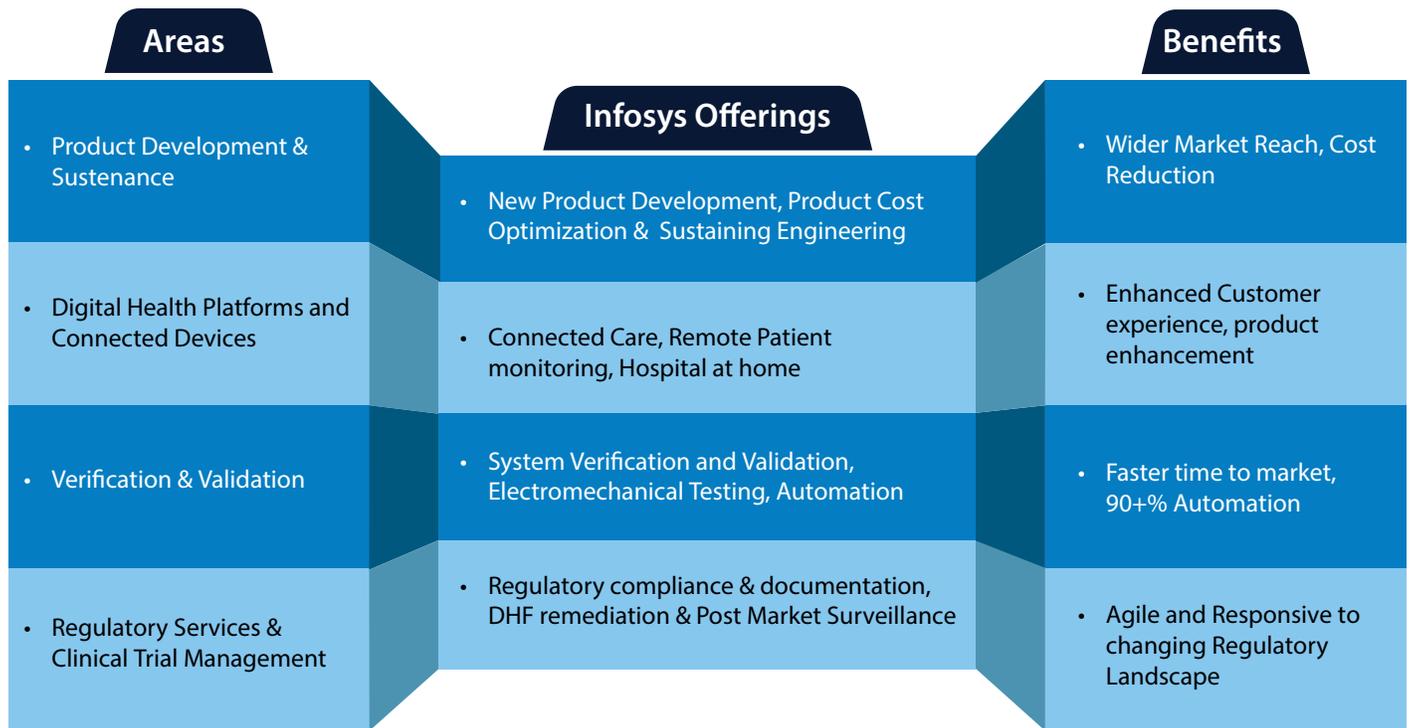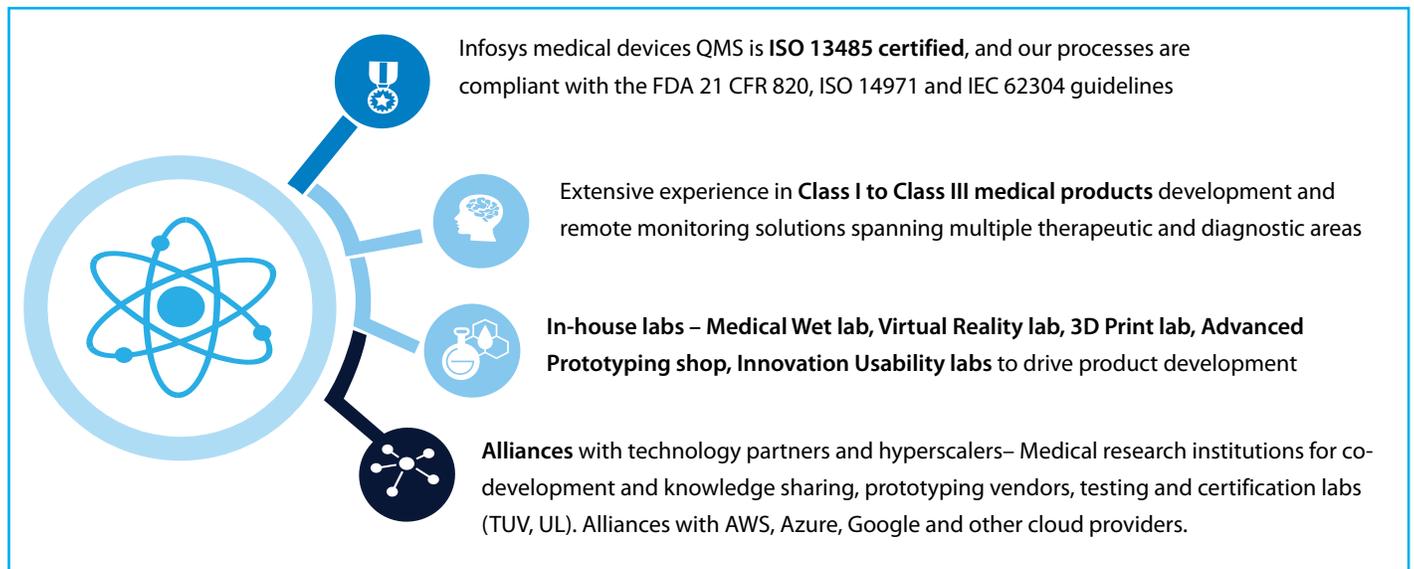
Our Service Offerings

We provide **end-to-end** services for medical devices, products and platforms, from concept to aftermarket support, encompassing mechanical, electronic, electrical, embedded and software engineering. Our multi-domain, multi-functional team of experts brings together the best of industry practices and processes and their experience to create solutions best suited for each client.

Early Innovation	Concept Design	Design & Development	Clinical Trials	Post Market Surveillance

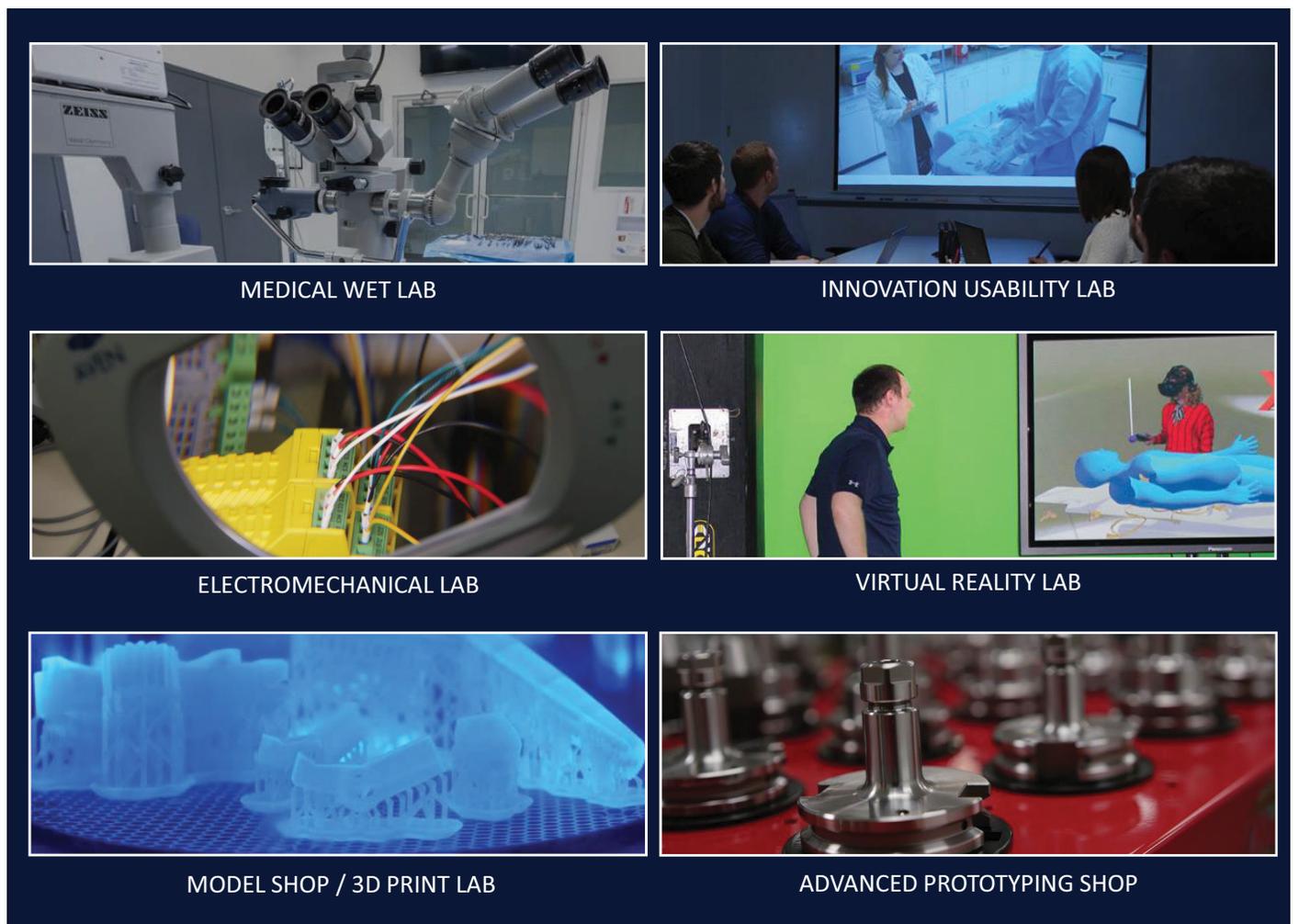| Market Research	Prototyping	Design Validation	Regulatory Submission & Approval	Product Sustenance
VOC / User Research	Industrial Design	Detailed Design (Electro-mechanical, firmware)	Regulatory Submissions	Value Engineering
Patient/Clinician Surveys	Concept Development	Software & Mobile Application development (SaMD)	Support to Compliance and CAPA	Product Cost Optimization (PCO) Platform
Insights	Medical Affairs	Digital Healthcare Platform development	Post Market Surveillance & Complaints Management	Engineering Change Management
Human Factor Engineering	Usability Labs & Studies	Verification & Validation	AR/VR Capabilities	Returned Product Investigations
		Regulatory Documentation	Insights and AI/ML	

Kaleidoscope Innovation, a wholly owned subsidiary of Infosys, headquartered in Cincinnati, Ohio, brings deep domain knowledge and understanding of the highly regulated Life Science industry, extensive experience in user research, insights and design, an understanding of clinical environments, strong product development capabilities across therapeutic areas, addressing human factors engineering, product design, UI/UX design, development and XR visualization.

Areas

- Product Development & Sustenance
- Digital Health Platforms and Connected Devices
- Verification & Validation
- Regulatory Services & Clinical Trial Management

Infosys Offerings

- New Product Development, Product Cost Optimization & Sustaining Engineering
- Connected Care, Remote Patient monitoring, Hospital at home
- System Verification and Validation, Electromechanical Testing, Automation
- Regulatory compliance & documentation, DHF remediation & Post Market Surveillance

Benefits

- Wider Market Reach, Cost Reduction
- Enhanced Customer experience, product enhancement
- Faster time to market, 90+% Automation
- Agile and Responsive to changing Regulatory Landscape

Infosys Value Proposition

Infosys medical devices QMS is **ISO 13485 certified**, and our processes are compliant with the FDA 21 CFR 820, ISO 14971 and IEC 62304 guidelines

Extensive experience in **Class I to Class III medical products** development and remote monitoring solutions spanning multiple therapeutic and diagnostic areas

In-house labs – Medical Wet lab, Virtual Reality lab, 3D Print lab, Advanced Prototyping shop, Innovation Usability labs to drive product development

Alliances with technology partners and hyperscalers– Medical research institutions for co-development and knowledge sharing, prototyping vendors, testing and certification labs (TUV, UL). Alliances with AWS, Azure, Google and other cloud providers.

State-of-the-Art Labs

MEDICAL WET LAB

INNOVATION USABILITY LAB

ELECTROMECHANICAL LAB

VIRTUAL REALITY LAB

MODEL SHOP / 3D PRINT LAB

ADVANCED PROTOTYPING SHOP

Representative Successful Engagements

Infosys has partnered with many medical device clients to conceptualize, design, prototype, develop, verify, and validate end-to-end medical devices and systems associated with regulatory documentation and support post-market activities. We also assist our clients in sustaining legacy products through our sustenance engineering and remediation offerings.

iOS-based clinic Programmer development for Cardiac Loop Recorder

Class II Medical Application developed in a multi-tier mode with UI based on Hybrid framework, along with business layer in native iOS components and C/C++ based modules for telemetry

Faster time to market for the application within a period of 12 months
Reduced cost by providing a COTS mobile based medical device solution instead of a proprietary hardware-based solution

Developed end-to-end diagnostic imaging system for emerging markets

Complete Product design, Hardware, Firmware and software development. Prototype build/Assembly Reliability, durability, DVT testing, Documentation, Certification and Mass production

Optimized Product cost by 35%
Reduction in Time To Market by 6 Months

Develop a patient-centric digital solution SaMD for Diabetes Care Management

Patient centric mobile apps and cloud platform for coaches to communicate with and track diabetic patients.
Wireless Data Collection, GUI development, iOS/Android Mobile Apps, Data transfer to Cloud

Automated reminders and collection of readings from glucometer increased compliance.
Increased patient engagement

Self Care Management using Machine Learning
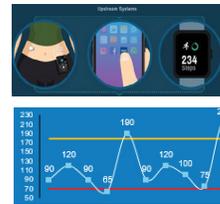
SaMD Solution development for corelating data from multiple streams and provide useful insights for patient and HCP.
Patient data security and SaMD Regulatory Compliance
Pluggable into any existing patient engagement solution

Meaningful insights helping patients manage their daily decisions
65% of Lows avoided with predictive alerts
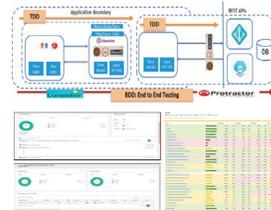44% of Highs avoided with predictive alerts

Generate regulatory strategies and work with regulatory agencies to meet ambitious objectives

Designed most efficient strategy for a novel product with an uncertain regulatory pathway.
uncertain regulatory pathway
Conducted Q Submission meetings leading to novel clinical evaluation approach.
Implemented Quality Management System

Successful 510(k) submission supported with clinical evidence
Expanded support to include EU MDR transition implementation

Test Automation Framework for an IVD domain customer

Test automation framework development
Device simulator for component level testing
Test planning, Test automation & Execution
Test Framework validation
Execution and reports

Automated Cloud Infrastructure setup and monitoring using Infrastructure as Code Automation
Improved time to market
High level of automation using simulators

For more information, contact askus@infosys.com

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