Overview and Challenges

The medical device industry is witnessing transformational changes due to globalization, an uncertain macroeconomic climate, changing regulations and technology advancements. To succeed, we believe device manufactures need to focus on the following:

**Converging technologies and “consumerization” of healthcare**

The rapid penetration of technology in provisioning systems necessitates a seismic change in device development strategies, a sharper focus on consumer preferences and connected care as well as investments in enabling technologies such as cloud, mobility, and healthcare analytics.

**Maintaining an innovative edge despite strained R&D budgets**

Increased taxation on medical device manufacturers due to new healthcare regulations in mature markets put additional pressure on the bottom line and already strained R&D budgets. Device manufacturers need to rethink their core value and identify opportunities to improve R&D productivity.

**Regulatory compliance without affecting cycle times**

Device development is being saddled by compliance and regulatory initiatives impacting development cycles, requiring new investment in lifecycle processes.

**Market opportunities with localized offerings**

Manufacturers are looking to emerging markets for growth. Success will depend heavily on product offerings built for global markets and localized to meet specific regional requirements. This needs effective management of new global value chains, consumer preferences, regulatory environments and business models that are often unfamiliar and complex.
Multi-disciplinary capabilities to deliver innovative care solutions
Infosys combines its expertise in cloud, mobility, analytics and device engineering with domain experience in clinical processes, user ergonomics and standards to help clients define and realize next generation medical devices. Cross-pollinating best practices from product development programs across industries and business situations, we help clients deliver innovative healthcare solutions from product conceptualization to manufacturing.

Design for Globalization
With investments in technology, component engineering and agile processes, Infosys provides a more cost effective and efficient product development alternative for medical device companies. Our managed product development approach institutionalizes development of global products that can be easily localized, easing entry into new markets. It is supported by a broad ecosystem of academia, medical experts and laboratories in developed and as well as emerging markets.

Sustain your innovation potential even with strained budgets
Our clients leverage our investments in innovation labs, third party compliance, R&D partnerships and advanced engineering expertise that help them ride the technology curve with significantly reduced CAPEX. We identify and optimize key levers that can be used to drive sustained cost from the product development process using our Value Analysis Value Engineering (VA VE) cost reduction methodology.

Fast-track regulatory compliance
Infosys’ Compliance & Regulatory Services and Product Lifecycle Management (PLM) solutions help clients reduce the time for regulatory submissions while improving efficiency. Infosys offerings are complaint to ISO 13485, ISO 14971 and ISO 62304 ensuring preparedness for meeting increasingly stringent & evolving regulatory requirements and safety protocols to rapidly secure RoHS, FDA 510K, PMA, CE approvals.
Service Offering

We have successfully partnered with our clients through the complete medical device value chain.

- **Plan**
  - Scientific Innovation Solution
  - Concept Design (Mechanical & Electro-Mechanical, Software, Firmware)
  - Detailed Design (Mechanical & Electro-Mechanical, Software, Firmware)
  - Design Review and Validation
  - Variant Design Generation, Value Analysis, Value Engineering
  - Digital Manufacturing Support – Design Transfer, Creation/Optimizing CNC programs, Gerber files, tool and die design etc.
  - Plant Design, Automation and MES Implementation and Support
  - Support to Compliance Management and CAPA
  - Publications and PMA/S10 (K) Submission Support
  - Documentation & Compliance as per ISO13485, 21 CFR Part 820, IEC62304, IEC60601
  - Risk Management as per ISO14971
  - Product Marketing Publications – Digital Asset Management, Web Presence, Next Generation Commerce etc.

- **Concept**

- **Design**

- **Validate**

- **Production**

- **Support**

- Engineering / R&D
  - Concept Design (Mechanical & Electro-Mechanical, Software, Firmware)
  - Detailed Design (Mechanical & Electro-Mechanical, Software, Firmware)
  - Design Review and Validation
  - Variant Design Generation, Value Analysis, Value Engineering
  - Digital Manufacturing Support – Design Transfer, Creation/Optimizing CNC programs, Gerber files, tool and die design etc.
  - Plant Design, Automation and MES Implementation and Support
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- Manufacturing

- Quality/Regulatory

- Sales and Marketing

- Emerging Technologies (Mobility, Cloud Solutions), Business Process Outsourcing, High Value Consulting, Organizational Change Management, Learning Enablement etc.

- Infrastructure Engineering and Management – Contact Centre, Hardware, Software, Data Center, Network, Technology Architecture etc.

- Enterprise Systems including ERP, CRM, PLM, Financial Systems, HR, Legal etc.
Representative Successful Engagements

A US-based, global leader in cardiac rhythm management partnered with Infosys for design, development and verification of multiple releases of software for products to be launched in various geographies. Infosys helped the client obtain supplementary PMA, CE approvals besides reducing the product cost by 30%.

Partnering with a global leader in sleep management solutions Infosys developed a standalone and web-based solution for remote patient monitoring along with the hardware, firmware and data management solution for analysis and reporting. We also created all design documents and verification reports which helped in rapid FDA 510K filing and approvals.

For a global leader in obstructive sleep apnea home testing, Infosys designed an innovative cloud-based user portal on Salesforce.com to broaden the reach and efficiency of the diagnostic solution suite. The portal provided web interfaces with third-party applications to access and analyze patient data immediately upon receipt of the completed test thus reducing the report cycle time by two days.

For a leader in radiology products, Infosys developed a web-based radiology workflow system that automates the workflow significantly reducing per case time for the radiologist.

Partnering with a leader in diabetes disease management Infosys developed the diabetes data management system used by patients to upload their sugar and carbohydrate intake for healthcare professionals to monitor and provide guidance. The product works on multiple platforms and was released in multiple languages across geographies with significantly reduced effort and time.
Six of the top 10 device manufacturers come to Infosys for help in creating and implementing the strategies needed to tackle these areas, key to building products powered by the latest in medical technology.
Our clients work with us to take advantage of world class quality frameworks with processes certified at SEI CMMI Level 5, ISO 9001-2000, ISO 13485, ISO 14971, and IEC 62304, ISO27001 levels. These along with our knowledge of IHE and related standards such as HL7, DICOM, IEEE 11073, HDP, IHE Profiles like LAW, IDCO ensure that quality frameworks are designed and adapted in a way consistent with the prevailing standards driving the medical device industry.

To remain best in class, product development must be backed by a commitment to relentless innovation. For Infosys, these investments include the creation of a managed service for new product development, built along lean manufacturing principals, featuring a ready ecosystem of suppliers, collaborative relationships with hospitals, clinics and medical specialists. Our offering features a “design for compliance” build approach that enables swift prototype development, even in the absence of a complete product specification. This approach can be used to develop a broad range of Class I, II and III devices and solutions from diabetes management to remote health monitoring to radiology workflow systems.

The Medical Devices CoE serves as our “think tank” by focusing on the latest industry developments and problems with the goal of developing solutions and proofs-of-concept (PoCs) that address them. Standards-related work includes IHE IDCO and LAW profiles, while PoCs have been built for remote vital parameter collection for blood pressure and weight via smart phones and remote patient monitoring.

Training in key initiatives and special topics is coordinated by the CoE with our Medical Device Academy, an institution dedicated to the education and certification of Infosys employees in a broad range of related regulations and technologies. Programs can be extended and customized per client engagement needs and generally include a curriculum featuring mechanical, software and electronic competency development. Representative topics range from the basics of ECG, to the application and use of implanted devices and remote patient monitoring, pain management, neuromodulation, new product development in medical devices and RF design. A five-level certification framework, mandatory for all practice employees, is offered with a special focus on cardiac domain certification covering diseases, diagnostic and treatment devices. Certifications covering FDA and EU device classification, industry standards (such as IEC60601, IEC62304, 21 CFR Part 820 and Part 11, ISO13485, HIPAA, EU Directives) and hazard analysis are also offered.