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# SOFTWARE PRODUCT SERVICES: MEDICAL DEVICE ENGINEERING

The healthcare and medical device industry is undergoing a transformation in the way solutions and devices are being developed. This is predominantly being driven by enforcement of tighter controls and stricter regulations by regulating agencies such as the FDA and because of government policies and acts towards accountable healthcare delivery for better patient outcome. Medical device companies have to identify mechanisms to drive innovation to address market needs and resolve challenges of longer device development cycles and optimize development and production costs.

It is imperative for the medical device companies to adopt a strategic approach to stay ahead of the innovation curve by leveraging technology advancements in multiple areas such as mobility, wireless, cloud, and analytics. At the same time, they can derive overall reduction in cost of design and development and faster time to market by leveraging distributed global engineering services.

Infosys Medical Devices Engineering practice has helped multiple medical device companies to design, develop, and verify medical device software for providing diagnostic and therapy solutions. Leading medical device manufacturers have benefitted from Infosys Engineering services and solutions in some of the following key areas:

1. Class I to Class III device development
2. Test center of excellence for verification and validation
3. Remote patient monitoring solutions
4. Mobile enablement and development of mobile medical applications
5. DHF creation and maintenance and support for regulatory submissions for FDA and CE

## Infosys software product services offerings

### Application software

- User interface design and development
- Standalone and Web applications development
- Device connectivity and workflow automation using IHE, IEEE 11073, HL7, and DICOM standards
- Auditing, logging, and reporting
- Tabular, graphical on-screen, and PDF report creatio
- Internationalization and localization

### Connectivity enablement

- Wireless enablement of devices using technologies like Bluetooth, BLE, ZigBee, WiFi, GSM / GPRS
- Device communication using RS232 or USB interfaces
- Data transfer using POTS modem and ISPs
- Data transfer to back-end systems using various protocols such as SSL, HTTP, SOAP, TCP / IP

### Mobile enablement

- Mobile OS customization
- Native, Web, and hybrid patient and clinician application development on Android, iOS, and RIM platforms
- Test framework development and automation
- Data communication over Bluetooth, BLE, USB, or Wifi

### Remote patient monitoring

- Device data collection using standard protocols and wired / wireless technologies
- Alerts and alarms generation and notification
- Data management and reporting
- Data security and privacy handling
- Integration with EMRs / PHRs and business systems
- Patient- and clinician-centric portals and applications

### Verification and validation

- Hub-and-spoke model based global test execution
- End-to-end medical system verification
- Test automation
- Tools validation and qualification (OTS, SOUP qualification)
- Application and firmware verification
- Verification of mobile medical applications

## Infosys advantage

- Medical device academy with focus on trainings and certifications for medical domain, applicable processes, and standards
- ISO 13485-certified engineering practice with a high focus on quality and processes compliant to ISO 14971 and IEC 62304. Infosys has helped clients with multiple products approval through CE or FDA
- Extensive experience in Class I to Class III medical product development and verification that includes CRM and areas such as neurology, radiology, diabetes, sleep apnea
- Alliance with technology partners – Microsoft, IBM, Oracle and Redhat, hospitals, test and certification labs; alliances with research institutes for voice-of-customer and emerging market product development
- Center of excellence across medical devices and mobility focusing on latest developments in the medical domain

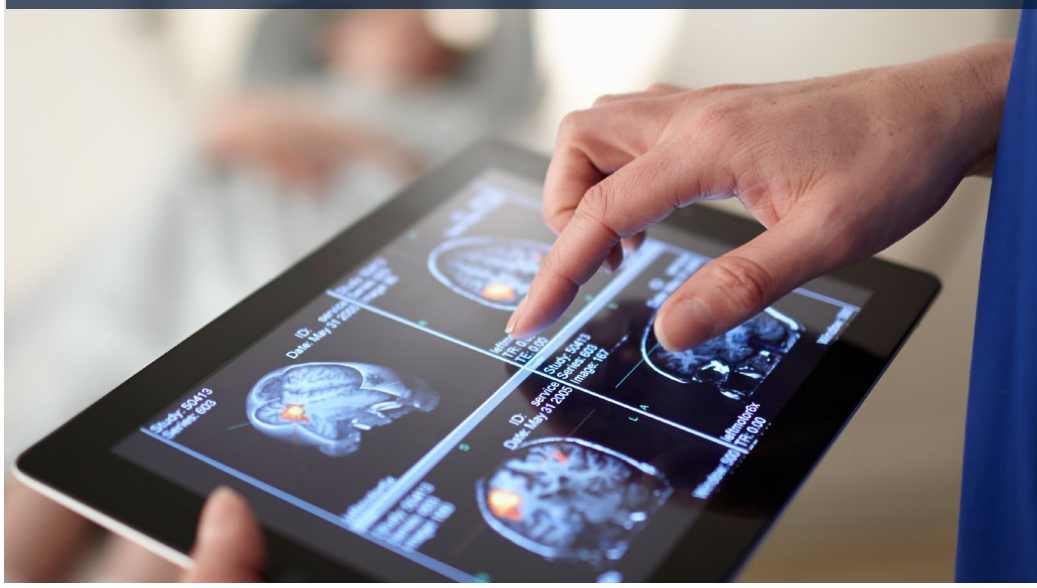
## Case study

### Client:

A leading cardiac rhythm management class III device manufacturer

### Client Requirement:

The client wanted a strategic R&D partner to help with development and verification of their implanted and external devices in order to lower the total cost of development and reduce turnaround time.



## Infosys services delivered

- Firmware, application software, mobile, and hardware design and development
- Covering entire ecosystem of implanted PG devices, home monitor, programmer, mobile applications, and remote patient monitoring products
- Test strategy definition and test protocols development
- Test automation and test execution
- Tools and OTS qualification
- Formal execution and creation of verification report
- Design history file (DHF) creation
- Multiple enhancement and maintenance releases

## Business impact

- Flexible staffing with quick ramp ups for urgent needs
- Offshore development center with a dedicated lab to support complete formal execution
- Cost reduction in the range of 30 – 40 percent
- Year-on-year productivity improvement of 3 – 4 percent
- Improved time-to-market

For more information, contact askus@infosys.com

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