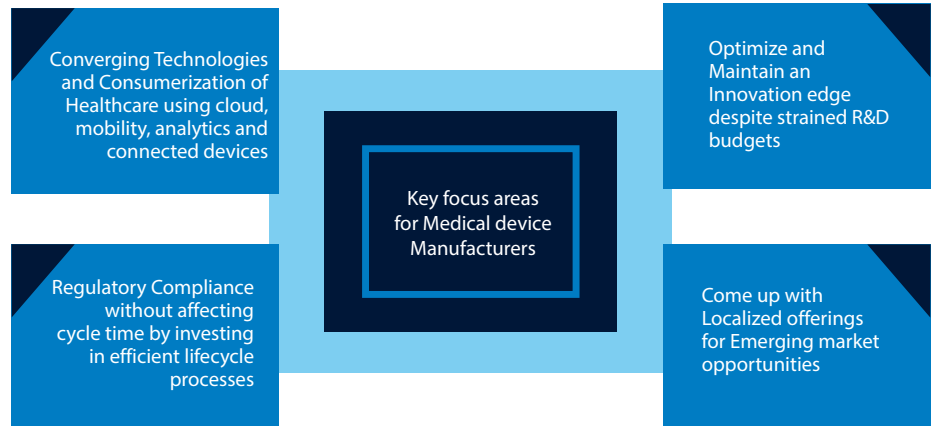


# INFOSYS MEDICAL DEVICES PRACTICE

## Overview

The medical device industry is witnessing transformational changes due to globalization, changing regulations and technology advancements. To succeed, device manufacturers need to focus on the following areas:

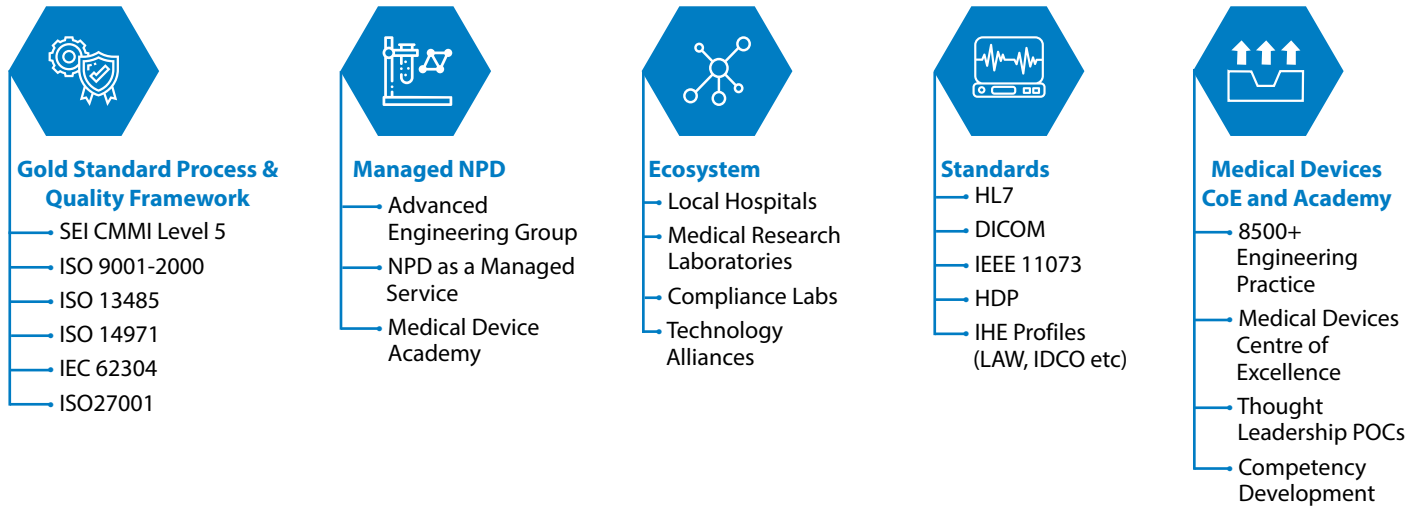


## Service Offerings

Infosys has an extensive suite of offerings that cater to these needs, having successfully partnered with multiple clients through the complete medical devices value chain.



<b>Hardware design and re-engineering</b>	<ul style="list-style-type: none"> <li>• Design &amp; development of electronics hardware, embedded firmware and mechanical components</li> <li>• Rapid prototyping</li> <li>• BSP &amp; device driver development</li> <li>• Data acquisition and digital signal processing</li> <li>• Device connectivity enablement and gateway development</li> <li>• Sustainance engineering</li> </ul>	<ul style="list-style-type: none"> <li>• CAPA analysis</li> <li>• RoHS compliance</li> <li>• DHF remediation</li> <li>• Unique Device Identifier(UDI), Packaging and Labeling</li> <li>• Emerging market research</li> <li>• Supplier identification &amp; qualification</li> <li>• Value analysis and value engineering</li> </ul>
<b>Software Product Services</b>	<ul style="list-style-type: none"> <li>• End-to-end development services</li> <li>• Engineering solutions for remote patient monitoring</li> <li>• Data connectivity and integration using standard protocols</li> <li>• GUI design and development</li> <li>• Mobile based applications for patients and clinicians' use</li> </ul>	<ul style="list-style-type: none"> <li>• Regulatory support services (DHF creation and 510(K) submission)</li> <li>• Product transformation services (globalization, legacy modernization, and cloud enablement)</li> <li>• Product specialization services (CDCI and DevOps)</li> </ul>
<b>Verification and Validation</b>	<ul style="list-style-type: none"> <li>• End-to-end medical system verification</li> <li>• Test automation</li> <li>• Tools validation and qualification (OTS, SOUP qualification)</li> </ul>	<ul style="list-style-type: none"> <li>• Application and firmware verification</li> <li>• Verification of mobile medical applications</li> </ul>
<b>Product Lifecycle Management</b>	<ul style="list-style-type: none"> <li>• PLM consulting                             <ul style="list-style-type: none"> <li>• PLM strategy</li> <li>• Process study</li> <li>• Package evaluation</li> </ul> </li> <li>• PLM implementation                             <ul style="list-style-type: none"> <li>• Solution architecture</li> <li>• Configuration &amp; customization</li> <li>• Deployment and roll out</li> <li>• Application maintenance services</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• PLM value chain services                             <ul style="list-style-type: none"> <li>• Integration</li> <li>• Performance management</li> <li>• Migration and upgrade</li> </ul> </li> <li>• Training and roll out support</li> </ul>
<b>Plant automation and control systems</b>	<ul style="list-style-type: none"> <li>• Laboratory information management system</li> <li>• Manufacturing intelligence and integration (MII)</li> </ul>	<ul style="list-style-type: none"> <li>• Manufacturing execution systems / connected manufacturing</li> <li>• Plant application support</li> </ul>

# Infosys advantage



Infosys has strong expertise in design, development, verification and validation of Class I to Class III medical devices products covering software, embedded hardware, mechanical, firmware, and mobile applications. Some of the products and systems we have worked on are:

- Implanted pacemakers, ICD, and CRT devices, monitoring and programming devices
- Neuro-modulation devices like Spinal Cord Stimulation and Deep Brain Stimulation
- On-body patch for collecting vital cardiac parameters
- Mobile apps and remote patient monitoring solutions
- Radiology products and work flow management systems
- Electro-physiology devices
- Sleep apnea diagnostics and treatment devices
- Glucometers for personal and hospital use, and personal care devices like BP monitors, pulse oximeters, heart-rate meters

For a medical device major in cardiac rhythm management space		
<b>Infosys Role</b>	<ul style="list-style-type: none"> <li>• Established offshore R&amp;D center for Class I, II and III medical devices and applications</li> <li>• Development and verification of remote monitoring system and clinician programmer devices</li> <li>• Mobile enabled access for clinician for alert monitoring</li> </ul>	
<b>Key Business Benefit</b>	<ul style="list-style-type: none"> <li>• Reduction in the R&amp;D cost for the client by 40-50%</li> <li>• Reduction in the product release life cycle by 40-45% thereby enabling more releases per year</li> <li>• Mobile based alert monitoring yielding improved patient outcome</li> </ul>	
For a device major in Sleep Apnea solution space		
<b>Infosys Role</b>	<ul style="list-style-type: none"> <li>• Partnered with client to develop next-gen data management solution for multiple Sleep Apnea therapy devices for monitoring progress and compliance of therapy by patients</li> </ul>	
<b>Key Business Benefit</b>	<ul style="list-style-type: none"> <li>• Transformed legacy product architecture to a global, flexible and scalable architecture</li> <li>• Helped client get FDA 510(K) clearance for the product</li> </ul>	

For more information, contact [askus@infosys.com](mailto:askus@infosys.com)



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