

Enabling a healthier tomorrow

MEDICAL DEVICES

HCL ENGINEERING AND R&D SERVICES

The Environment Today

How can the current healthcare and medical device infrastructure meet the requirements of a growing global population? The simple answer is that it can't. Providing scalable and affordable solutions to patients will require new approaches to leveraging technology. HCL is a recognized leader in the medical device outsourcing space, providing fast and cost effective end-to-end solutions across a variety of Class I, II and III devices. HCL offers "Concept to Manufacture" R&D outsourcing services in concept design, prototype development & validation; pre-clinical and clinical development; manufacturing and plant automation; sales & marketing; enterprise IT functions and obsolescence management.

Medical Devices Service Offering

New Product Introduction

Overview

- Product Conceptualization
- Design, Development and Testing
- Regulatory Compliance

Services

Hardware Engineering, Firmware and Embedded Software Engineering, Mechanical Engineering, Industrial Design, Test Engineering, Regulatory Compliance support, Documentation

Enablers

- Medical Quality Management System (MQMS)
- Documentation and processes compliant with FDA requirements
- 510(k), IDE and PMA: submission-ready
- Centers of Excellence (CoEs) for Industry 4.0, Mobility Industrial Design, FEA, IV&V

Value Analysis and Value Engineering

- Cost reduction
- Size reduction/miniaturization
- Re-engineering products for Emerging Markets
- Feature Enhancements
- Interoperability Initiatives

Continuity and End-of-Life Engineering

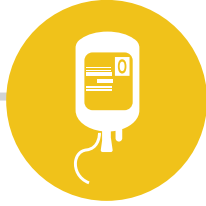
- Sustenance engineering
- End of Life Support
- Obsolescence Management
- Porting
- Migration
- Modernization
- RoHS /IEC- 3rd edition Compliance

Embedded Software Development, Verification and Validation
Design, Tooling, GUI Design, System Integration and Testing, DfX Analysis, Prototyping,
Documentation

ISO 9001 (IATF 16949), ISO 13485 certified
Compliant with 21 CFR Part 11, 21 CFR Part 820, IEC 62304:2006, IEC-60601
documentation
Mechanical Design, Imaging, Reliability Engineering, Wireless Design, User Interface Design,

HCL has worked on medical devices in the areas of





Infusion systems



Orthopedic



Diagnostic Imaging



Neurology

and many more...



Service Line Units



Acceleration

- Platform Acceleration Suite

Value

- Accelerated Functional Testing
- Performance Engineering
- eDAT
- VAVE

Technology

- Product Intelligence
- Internet of Things

HCL in Medical Devices

*A partner
to 7 of the top 10
medical devices
companies*

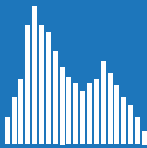
*11+ years of
experience in medical
devices alone. 30+ years of
engineering heritage and
several complex mission-
critical electro-mechanical
products developed from
concept to launch*

*Partnerships with institutes
such as Human Factor
International, IITs, IISCs.
Participant in
Confederation of Indian
Industries (CII) committee
on regulatory guidelines
for medical devices in India*

*Conformance to CMMi
Level-5, ISO-9001,
ISO-13485, BS7799/ISO
27001, ISO-14971,
ISO/IEC 17025, AAMI
SW68:2001 standards*



*Centers of Excellence
(CoEs) for Industrial
Design, Imaging,
Reliability Engineering,
Wireless Design, User
Interface Design,
Mobility Industrial
Design, FEA, IV&V*



*Mature project
and risk management
processes with QMS
confirming to FDA
regulations audited
by the world's leading
medical OEMs*

*%
PROFIT*

*Compliant to 21
CFR Part 11, 21 CFR
Part 820, SW: 68/
IEC 62304:2006, IEC
-60601-1-2-3-4,
SHA, HL7 and
DICOM processes*

*Involved
in the
development of
90+ devices*

*Largest medical
device practice
among Indian
outsourcing
providers*

Experiences Engineered for our customers (Case Studies)

1 For a medical device major, HCL did complex design and development on a cutting edge product - a drug delivery system for Class III medical devices. A time to market reduction of 30% was achieved by adopting ISO13485 compliant development activities including regulatory support.

2 HCL helped a pharma major move into the medical devices space through market research, VOC & ideation of concepts and is now responsible for the design and development of selected concepts.

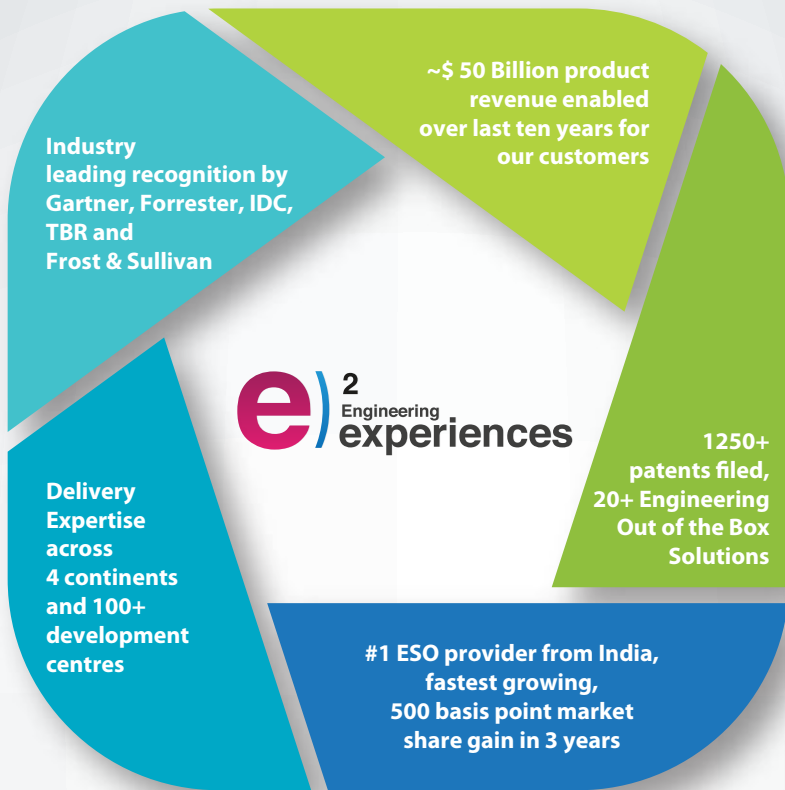
3 For a fortune 100 company, a huge workforce ramp up of 1000 people was done through judicious offshoring and by setting up a COE through HCL's assistance at onsite locations. A framework based approach ensured predictable (18 months), scalable results for costs and margins. Committed IP generation resulted in innovation in technology, processes and products.

4 For a class II medical device, HCL developed product DFMEA and had complete ownership of SHA and software DFMEA documents. It resulted in 11% additional coverage, leading to end-user scenario addition in market requirement spec and higher coverage on safety & product features implementation. Traceability creep in testing stage was reduced to less than 4% with 95% traceability achieved before verification and validation started.



Look here





Hello, I'm from HCL's Engineering and R&D Services. We enable technology led organizations to go to market with innovative products and solutions. We partner with our customers in building world class products and creating associated solution delivery ecosystems to help bring market leadership. We develop engineering products, solutions and platforms across Aerospace and Defense, Automotive, Consumer Electronics, Software, Online, Industrial Manufacturing, Medical Devices, Networking and Telecom, Office Automation, Semiconductor and Servers & Storage for our customers.

For more details contact: ers.info@hcl.com
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