



New product development made simple

With capability to support end-to-end NPD lifecycle, knowledge and skill of cross functioning, 1250+ patents filed, investment for in-house state-of-the-art labs, assured design quality and experience in emerging markets devices, get our comprehensive solution to simplify product development and redefine care.

HCL's Services across Product Life Cycle

Launch

- Design Transfer
- Regulatory Compliance Support - Documentation
- Computer System Validation
- ► Equipment Qualification IQ/ OQ/ PQ
- Manufacturing Process Validation
- ▶ CE Marking
- Data Analytics and Reporting
- Product Maintenance
- NABL accredited Testing Labs; and partnerships with certification bodies
- ▶ D&A Team with AI/ ML Techniques
- CSV Tool database





Verification & Validation

- ▶ Hardware Testing Board
- ▶ Functional
- Software Testing Unit
- Integration
- Sub-System
- ▶ Mechanical Testing
- ▶ Reliability testing

- Environmental and EMI/ EMC testing
- System Testing Functional
- ▶ Performance
- COTS/ Tool Validation
- ▶ HALT

- Static & Dynamic Code Analysis
- Unit Testing
- ▶ Integration Testing
- ▶ Software System Testing
- ▶ Tool Qualification
- ▶ Automated Testing
- In-house EMI/ EMC, Mechanical and Environmental Testing Labs
- ► Electronic Device Automation Testing Framework (eDAT)
- Mobile Test Automation Framework (MTAF)

 \uparrow

Design &

ment

- ▶ Requirements Definition
- ▶ System Engineering
- ▶ Architecture Design
- ▶ Hardware Design
- Software Design
- ▶ Mechanical Design
- ▶ Electronic Packaging
- ▶ Reliability Engineering
- Hardware and Software integration
- Pre-compliance testing

- Prototyping
- Embedded Software based Application Development
- Device Driver Development
- OS porting
- Protocol Driver Development
- ▶ Application Layer API
- **▶** BIOS
- Desktop, Client Server and Web based Solutions

- Device Management Framework
- Localization and Modularization
- Healthcare Enterprise Abstraction / Management
- Business Logic Development
- Interoperability -DICOM, HL7, IHE based Communication Protocol
- ▶ Security HIPAA

- ▶ Dedicated CoEs
- Industrial Design, Finite element analysis, Regulatory, Clinical, Usability, wireless
- ▶ Care Continuum Framework
- Medical Mobile Application Framework
- ▶ In-house Test Labs





GeometricStackup



Product Conceptualization

- Feasibility Study
- Human Factors Engineering and Cognitive
- Analysis
- Design directions for the new product
- ▶ Product Styling

- Concept Visualization through sketches
- Renderings (2D & 3D)
- Product Interface and Experience Design
- Mock-ups
- Consumer Immersion Design
- Usability analysis
- ▶ Embedded GUI
- PC based Applications Development
- Web Applications Development
- Custom UI Design

 Partnerships and alliances with leading surgeons and hospitals







Voice of Customer

- Contextual Research
- Observation and Qualitative research
- Fieldwork data collation
- Synthesis & analysis
- ▶ Feasibility
- Benchmarking
- CTQ definition

 Partnerships and alliances with leading market research agencies







New Product Development - HCL Experience



- ▶ Combining horizontal knowledge of Mechanical, Hardware, Digital, Embedded Software and Regulatory SME's
- Doctors, PhDs, Masters in relevant domains

Ability to support Product Performance & Competitive Benchmarking Studies

- ▶ Partnership with SR University, Chennai for Clinical Trials, Wet Lab testing
- ▶ Partnership with GLR Lab, Chennai
- ▶ Partnership with Johns Hopkins Medicine

Imaging Expertise

- ▶ Image Processing solution development
- Porting and optimization, Porting to FPGAs and ASICs
- Spatial and Frequency domain processing, Color image processing
- ▶ Closed loop Camera control
- ▶ Expertise on all major DSPs
- ▶ Real time imaging hardware design and development
- Large image processing application development

USD100 MN+ invested in labs

- Strategic Research, Innovation and Design for Experience Lab (STRIDE) for Industrial Design
- 9+ Design Assurance Labs (EMI/ EMC Testing, Radio Frequency lab, Environmental Chambers, DTV Signal generation, Wireless Network Simulation etc.)
- Mechanical Verification and Validation lab, Value Engineering Lab
- ▶ Mobile Testing, Smart Mobile Lab
- Customer specific labs

Regulatory, Clinical and PEBLES Center of Excellences (COE)

- 400+ biomedical, biotech, biochemistry, microbiology Engineering experience across all therapeutic areas
- ▶ PEBLES (Packaging, Material, Labelling, Sterilization, and biocompatibility) capability
- Former auditors with NB
- ▶ Former consultants for Regulatory bodies
- ▶ 1400+ trained resources supporting MDR and IVDR CE compliance for 18+ customers

Process Maturity and trained MQMS

- ▶ CMMI Level 5
- ISO: 13485
- ▶ BS 7799

0

Cross Leveraging Industry

Experience

across 10 Industry

Verticals at HCL

ISO: 27001

Case Study:

NPD Case study for a leading European MedTech company



Challenges

A leading device manufacturer of Immunoassay and Clinical Chemistry wanted to tap potential for smaller lab requirement. Their leadership decided to go ahead with NPD process with a short time line before competitors tap this potential.



HCL Solution

- ▶ HCL team showcased a good process and new product development knowledge from the sustenance engagement. The ability to scale up quickly with required skill sets helped in this program. HCL used its extensive experience of managing new product development lifecycle and co-creating 170+ Medical/ IVD Devices in the electro mechanical product design for this immuno-assay analyzer.
- ▶ Various center of Excellences within HCL helped to bring necessary flavors of NPD process. Mechatronics, Should costing, Value engineering CoE, Industrial Design team's functional expertise is used in this program. HCL could help devise new product development strategy and provide services to various functions like Reliability, system level testing, Test fixture development, design verification, thermal engineering, cable routing, fluidics, motion control areas.



Value Delivered

- Successfully completed the program with improved the time to market by 3 months
- ▶ Increased ownership for NPD of two subsystems till 2021

Case Studies:

Breast Biopsy System, Implantable Pain Relied System and Automated Drug Delivery systems



Business Objective

 Design & Development of Next Generation Breast Biopsy System



HCL Scope

- Complete Product
 Development involving SW,
 Electrical and Mechanical
 Design
- Prototyping and Feasibility Analysis for various modalities
- ▶ Load Characterization using Dynamometer setup
- Risk Analysis and Design Traceability
- ▶ Pre-Compliance testing
- Independent Verification and Validation



Value Delivered

- 20% reduction in the overall cost of the device and 1/3rd size reduction compared to the earlier variant
- 30% reduction in the overall biopsy cycle time and increased sample yield per biopsy
- Common hardware and software platforms for different modalities (X-Ray, Ultrasound and MRI)
- Completely automated biopsy procedure with vacuum assisted tissue sampling technique



Business Objective

Develop a Next Gen Implantable Pain Relief System



HCL Scope

- ► Feasibility, Prototyping and Product development
- ▶ Electrical and S/W for the pump and hand held unit
- Complete Electrical and S/W implementation & verification
- FMEA, SHA analysis and Traceability
- Validation testing



Business Objective

Development of Automated Drug Delivery System



HCL Scope

- System Design and Subsystem Specification
- Full Product Development involving hardware and software
- Product verification and validation
- DHF to meet FDA requirements



Value Delivered

- Ultra low power design to support 8 years of implantable life with Li-CFx battery
- 30% reduction in size compared to previous generation device
- ▶ Reduced timeline by 50%
- MRI compatible design.
 Device implanted in 450+ patients in Europe



Value Delivered

- PMA Approval & Product launch in US & Canada
- Architecture capable of absorbing all S/W changes
- ► FDA submission ready documentation
- Improved flexibility of the product and efficiency of development by utilizing knowledge base
- Work as an extended R&D team of the customer cutting across multiple cross functional teams
- Co-authored patent for the system architecture of UI and patient monitoring display

Contact Details:

Raj Varma

Regional Sales Director raj.varma@hcl.com



Hello there! I am an Ideapreneur. I believe that sustainable business outcomes are driven by relationships nurtured through values like trust, transparency and flexibility. I respect the contract, but believe in going beyond through collaboration, applied innovation and new generation partnership models that put your interest above everything else. Right now 150,000 Ideapreneurs are in a Relationship Beyond the Contract™ with 500 customers in 49 countries. How can I help you?

