



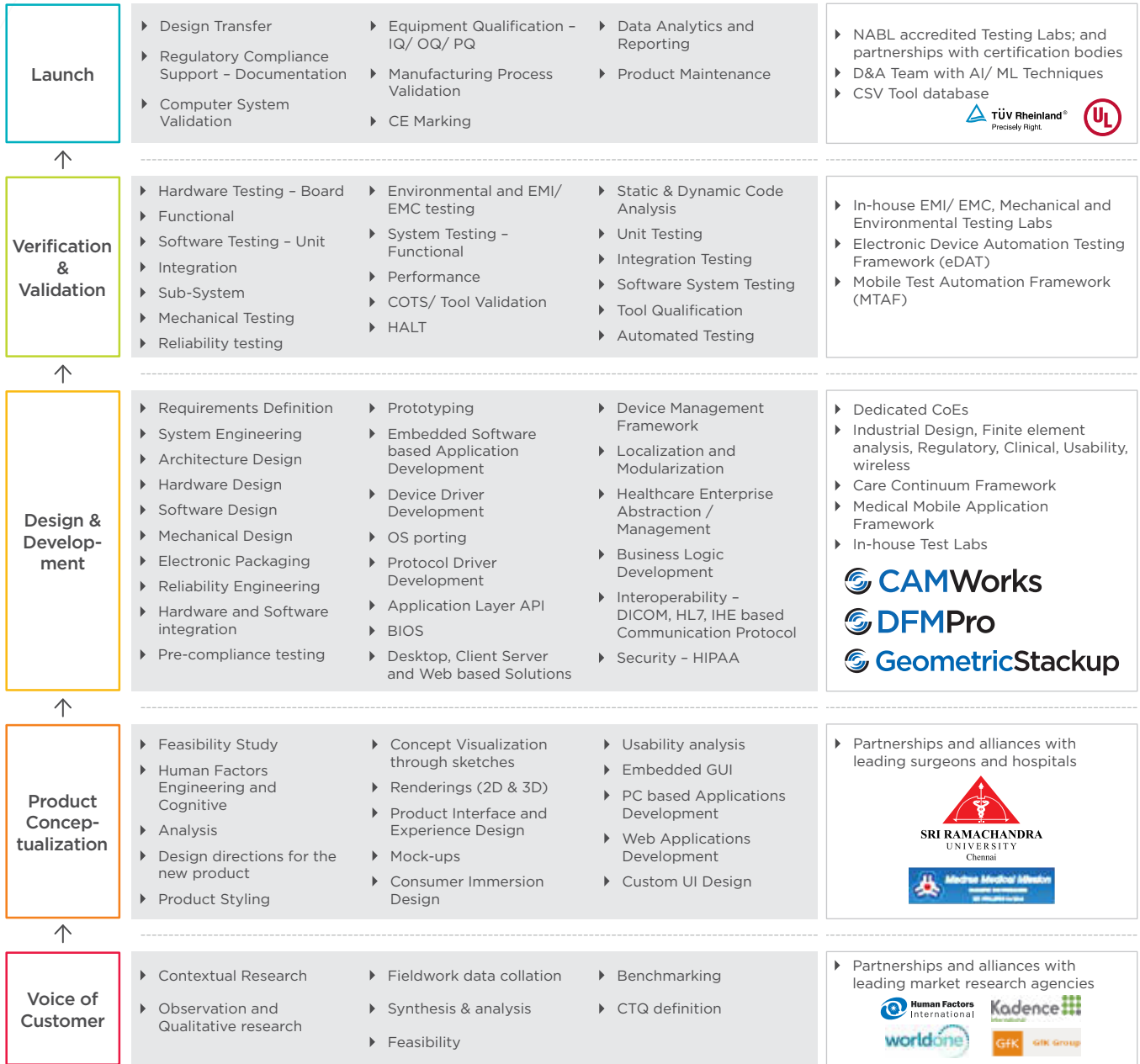
Growth partnership for a self-care centric lifestyle

 Innovation | Acceleration | Growth

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



New Product Development - HCL Experience

Cross Leveraging Industry Experience across 10 Industry Verticals at HCL

A Winning Team

- ▶ 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

USD100 MN+ invested in labs

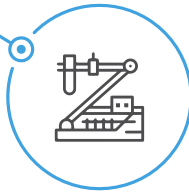
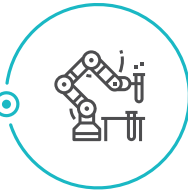
- ▶ Strategic Research, Innovation and Design for Experience Lab (STRIDE) for Industrial Design
- ▶ 9+ Design Assurance Labs (EMI/ EMC Testing, Radio Frequency lab, Environmental Chambers, DTV Signal generation, Wireless Network Simulation etc.)
- ▶ Mechanical Verification and Validation lab, Value Engineering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



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



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

- ▶ 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

For more information please contact ERS.info@hcl.com



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How can I help you?

HCL

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