




Growth partnership for a self-care centric lifestyle

 Innovation | Acceleration | Growth

Sustenance Engineering Services by HCL

HCL has co-created 250+ Medical and IVD devices. 85% of the resources work in sustaining legacy products for 9/10 Medical Device firms. Leverage our expertise in product feature changes, component engineering, product lifecycle engineering and adverse event management, to increase product life and revenue with higher customer retention.

HCL's Commercial Product Engineering Capability

Design Change Management

ECN / DCN Handling

Documentation

PLM / PDM Support

Change Request Creation	Design to Cost (DTC)	Regulatory and Compliance	Adverse Event Management	Component Engineering	Product Lifecycle Engineering	Product feature changes	Change Request Implementation
	<ul style="list-style-type: none"> • Tear Down Analysis • Benchmarking • Cost Modeling and Should Costing • Functional Analysis • Cost to Function Analysis • Feature Enhancements Test Automation • Remodel server infrastructure • Improve preventive maintenance in software • Enable Data analytics to reduce field visits by service person and device downtime 	<ul style="list-style-type: none"> • DHF Remediation • Product Re-certifications • Product Localizations • New Regulation Adherence • Enable Cybersecurity • Software updates for new Regulation adherence • SW enhancement - 62304 compliance for alarm standards • Clinical Evaluation Reports • PMS Activities • Periodic Risk File Updates 	<ul style="list-style-type: none"> • Field failure analysis & CAPA • Design Analysis • Design Support • Documentation • Test Method Development and Validation • Defect Fixes / Bug Fixes - (L2/ L3 support for issue analysis) 	<ul style="list-style-type: none"> • Technology changes • PCN / EOL review and support • Raw Material Changes • Tin Whisker Study & Mitigation in Component Level • Identification of Alternate Components / Vendors • Performance Improvement • Code refactoring 	<ul style="list-style-type: none"> • Manufacturing Issue resolution • DFM Study • Engineering Change Management • Root Cause Analysis • Risk Management • Reliability Engineering • Manufacturing test Software • EOL programming • IQ/OQ/PQ • SW porting / Migration • DevOps Implementation Support - TFS, GIT 	<ul style="list-style-type: none"> • Feature Enhancements • UX Localization (Multilingual Support) • Field issues management for Software • Enable connectivity • Software Changes Support for Electrical Obsolescence • Impact Analysis 	

Program Management

Risk Management

Communication Management

Stakeholder Management

Knowledge Management

Owning Sustenance Engineering – Why HCL?

HCL Enablers



Functional Expertise

- Cross leverage experience across carrying similar projects across multiple industries



Frameworks & Accelerators

- Proprietary modular, scalable, and highly customizable framework for verification and testing



Complete Ownership of Sustenance

- Demonstrable experience in ownership of product lines for leading MD customers



Resources with Knowledge of “Client” Processes

- Skilled Resources with Medical Device, Client Product & Process knowledge



HCL’s Centers of Excellence (CoE)

- Leverage HCL’s CoEs in Clinical, Regulatory, Quality, Imaging, Mechatronics, Testing, Reliability, Manufacturing Etc



Infrastructure

- Significant investment in in-house engineering labs, and tools

Value Delivered to “Client”



Predictability of Results

- Prior knowledge of expected business results and related cost. Monitor performance through SLAs



Focus on Innovation

- “Client” frees bandwidth for their engineers. Engage them in more innovative & critical projects



Improved Knowledge Management

- Leverage HCL’s pool of resources dedicated for “client” across multiple OpCos



Bring Flexibility

- HCL owns the responsibility for quick ramp-up/down with minimal impact on project & knowledge



Better Risk Mitigation

- Attrition, timeline, effort, outcome related risks are transferred from “client” to HCL



Lower Total Cost of Ownership for “client”

- Cost advantage for “client”. Utilize HCL’s onsite-offshore model to provide YoY benefits in cost



De-risk Transition with Proven Approach

- Track progress of sustenance ownership across phases of transition with proven metric systems & SLAs

HCL's Sustenance Engineering Credentials

Overall Experience

- 20+ years of after market support expertise
- 10+ leading Medical Devices OEM's extensively supported for sustenance
- 7500+ resources dedicated for Medical Devices
- Over 85% of HCL Medical Devices Revenue from Sustenance

Experience with Cross Functional Teams

- Demonstrable experience of working across Product Development, Quality, Regulatory and After market support
- Regulatory, Quality, Clinical, IVD Center of Excellence's
- Dedicated CoE's for VAVE, Cost Modelling, FEA, Reliability
- STRIDE and EDGE teams for industrial and product design
- Testing CoE for End-to-End Product testing services

Device Classification

- Class I, II & III



Solutions and Frameworks

- INTELLIGENT SUSTENANCE ENGINEERING (ISE)
- CARE Platform - Connected Assets in Regulated Environment
- ELECTRONIC DEVICE AUTOMATION TESTING (EDAT)
- PLATFORM FOR ACCELERATION OF NEXGEN ENGINEERING ANALYTICS (PANGEA)
- Intelligent Engineering Automation Platform (OPTIMUS)

Key Enablers

- Transition methodology
- Reusable components
- Low Volume Manufacturing
- Knowledge retention
- Ensuring quality
- Performance tracking
- Governance model
- Investments
- Value creation

Value Adds Generated

- **Customer 1:** >50% cost saving through 'Fee for Output' Model
- **Customer 2:** Cost Reduction in Flagship Product enabled increase sales by 14% YoY
- **Customer 3:** 30% reduction in Sustenance budget through HCL Flex Pool and Onshore-Offshore-Nearshore Model

FOR MORE INFORMATION, PLEASE CONTACT

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HCL

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