



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

	Design to Cost (DTC)	Regulatory and Compliance	Adverse Event Management	Component Engineering	Product Lifecycle Engineering	Product feature changes	
Change Request Creation	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	DHF Remediation Product Recertifications 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	 Field failure analysis & CAPA Design Analysis Design Support Documentation Test Method Development and Validation Defect Fixes / Bug Fixes - (L2/L3 support for issue analysis) 	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	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	Feature Enhancements UX Localization (Multilingual Support) Field issues management for Software Enable connectivity Software Changes Support for Electrical Obsolescence Impact Analysis	Change Request Implementation

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)

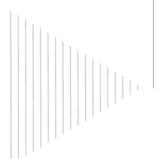
 Leverage HCL's CoEs in Clinical, Regulatory, Quality, Imaging, Mechatronics, Testing, Reliability, Manufacturing Etc



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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