



## Sustenance Engineering Services

With 20+ years of experience in MedTech industry, HCLTech has co-created 250+ Medical and IVD devices. Our sustenance engineering solution extends product life by building market relevant features which are regulatory compliant and cost effective. We are preferred sustenance engineering partner for 8 out of top 10 global medical devices companies.

# HCLTech's Commercial Product Engineering Capability

## Design Change Management

ECN / DCN Handling

Documentation

PLM / PDM Support

Change Request Creation

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

Change Request Implementation

## Program Management

Risk Management

Communication Management

Stakeholder Management

Knowledge Management

# Owning Sustenance Engineering – Why HCLTech?

## HCLTech 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



### HCLTech's Centers of Excellence (CoE)

- Leverage HCLTech'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 HCLTech's pool of resources dedicated for "client" across multiple OpCos



### Bring Flexibility

- HCLTech 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 HCLTech



### Lower Total Cost of Ownership for "client"

- Cost advantage for "client". Utilize HCLTech'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

# HCLTech's Sustenance Engineering Credentials

## Overall Experience

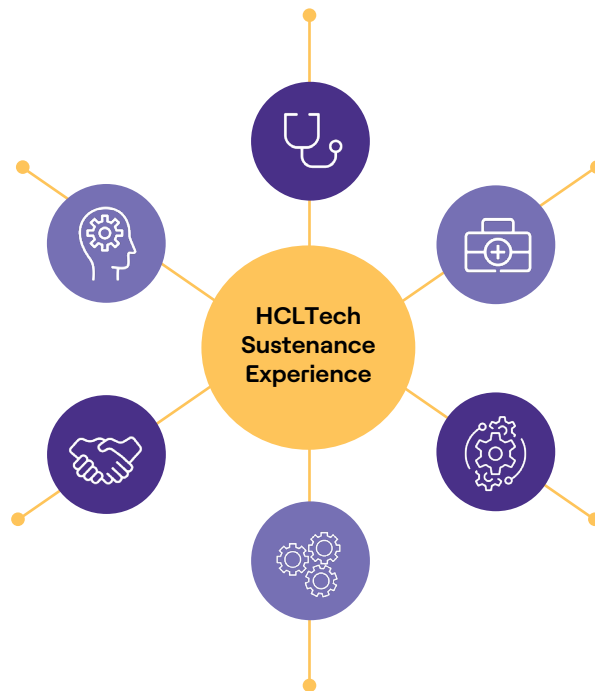
- 20+ years of after market support expertise
- 10+ leading Medical Devices OEM's extensively supported for sustenance
- 10000 resources dedicated for Medical Devices

## 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
- Platform for Acceleration of NEXTGEN Engineering Analytics (PANGAEA)
- Intelligent Engineering Automation Platform (OPTIMUS)
- EQUiP: Platform to deliver real-time quality insights and predictions

## 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 HCLTech Flex Pool and Onshore Offshore Near-shore Model

HCLTech is a global technology company, home to 219,000+ people across 54 countries, delivering industry-leading capabilities centered around Digital, Engineering and Cloud powered by a broad portfolio of technology services and software. The company generated consolidated revenues of \$12.1 billion over the 12 months ended September 2022. To learn how we can supercharge progress for you, visit [hcltech.com](https://hcltech.com).

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