

## PROCESS AND PRODUCT VALIDATION SERVICES

### DESIGN QUALITY ENGINEERING

- CTQ Definition
- Product / Design Risk Management
- Requirement Management
- Test Method Development & Validation
- Claims Testing & Benchmark Study
- DOE Run and Statistical Analysis
- Reviews and approvals for DHFs & DMRs

### REGULATORY & COMPLIANCE SERVICES

- Compliance, Safety & Packaging certifications
- Technical File Compilation for Regulatory Submission
- Standards Assessment & Mapping
- Requirement for Labeling and IFU
- Remediation
- Product Re-registration

### OPERATIONS & SUPPLIER QUALITY ENGINEERING

- Non-conformance Management
- First Article Inspection / PPAP Documentation
- Manufacturing Test Method Development & Validation
- Process Validation (IQ, OQ, PQ)
- Process Compliance and Monitoring
- Supplier Audit, Assessment, and Agreement Support
- Supplier Change Requests

### COMPLAINT MANAGEMENT

- Complaint Intake
- Complaint Evaluation and Classification
- Complaint RCA and CAPA Closure
- Field re-calls & MDR Reporting
- Post Market Surveillance Support



SIX SIGMA CERTIFIED PROFESSIONALS



ASQ CERTIFIED QUALITY ENGINEERS



ACCESS TO GLOBAL MEDICAL QUALITY AND REGULATORY STANDARDS



CLINICAL, MEDICAL AFFAIRS, AND BIO-MEDICAL ENGINEERING TALENT



KNOWLEDGE IN TOOLS (MINITAB, RCA & STATISTICAL TOOLS ETC.)



PROGRAM MANAGEMENT

### HCL'S REGULATORY CENTER OF EXCELLENCE



HCL's Regulatory Centre of Excellence with a 40+ member team has experience over the last 10+ years helping customers (including 9 of the top 10 medical devices companies) comply to the changing regulatory landscape.

HCL's Regulatory service offerings include Regulatory feasibility assessment, Standards & Regulations identification, support for Design for Compliance, Labeling requirements, Preparation of Regulatory Dossier, support for Localization, and Post-market support.

We have extensive experience helping our customers for Regulatory changes like ISO 13485, ISO 14971, IEC 60601x, IEC 62304, IEC 62366x, UDI, Cybersecurity, Mobile Medical Apps (MMA), ISO 10993x, et al.

Supported for 30+ country specific regulations & compliance.

Executed more than 30+ Regulatory projects for different types of Medical Device (Class 1, 2, 3)

# HCL EXPERIENCE IN PROCESS VALIDATION

Products – Class I, II & III | 20,000 Man Months



Cardiovascular & CRM



Orthopedic



Diagnostic Devices



General Surgery



Urology



Disposables & Infusion Systems

- Risk Management
- Validation – Test methods, CSV & Tool
- IQ OQ PQ
- Production Process Control
- Test Fixture Design & Development
- Requirement Traceability Matrix

FDA 21 CFR 820

MDD 93-42 EEC

ISO/EN 14971

**DHF Remediation**

100+ DHFs

300+ FTEs

40,000 Man Months

## HCL EXPERIENCE ON QUALITY & COMPLIANCE - REMEDIATION

### M&A - Integration

DHF Remediation for Class III Ventricular support devices

### Standards Compliance

Risk File Remediation for Class II Combination products

Technical File Remediation for Class II & III Orthopaedic Implants & Surgical Devices

Process validation / remediation for Coronary devices

Process validation / remediation for general surgery devices

### Non-Compliance

Process validation / remediation for Class III Cardiac Rhythm management Device

Process validation / remediation for Class II urology devices

### Legacy

DHF Remediation for Class II life sustaining Devices

DHF Remediation for Class II Combination products

Process validation / remediation for Class II surgical sutures



www.hcltech.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 116,000 Ideapreneurs are in a Relationship Beyond the Contract™ with 500+ customers in 32 countries. How can I help you?

*Relationship*<sup>™</sup>  
BEYOND THE CONTRACT

BI-103224313770843-EN00GL

**HCL**