HCL

# Growth partnership for a self-care centric lifestyle

Innovation | Acceleration | Growth

## Quality engineering services

# HCL quality engineering and consulting services

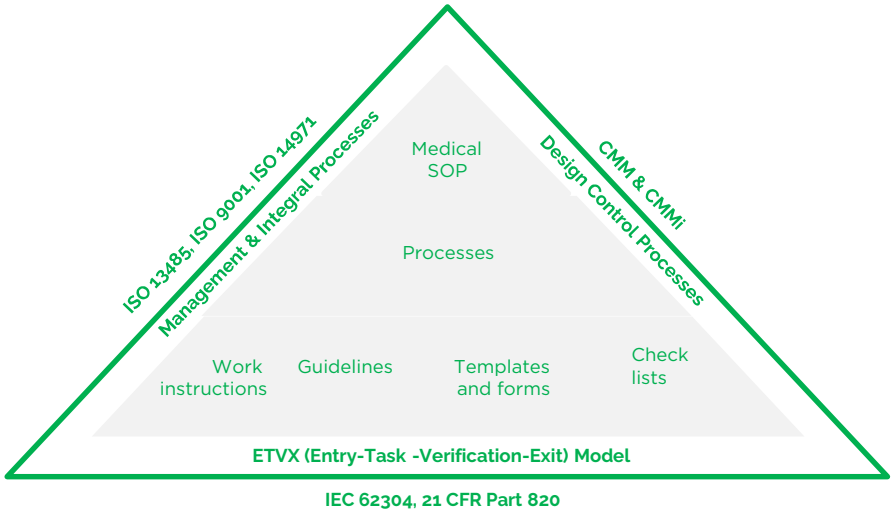
| | Footprint | Ownership | | | Team size |
|---|---|---|---|---|---|
| QMS process definition | 14 Customers | 15 QMS definition remediation | Independent QMS audit for 4 OEM's | | 50+ Associates |
| Design quality | 18 Customers | Design process compliance | Quality metrics definition and tracking | Risk management | 100+ Associates |
| Manufacturing quality | 8 Customers | MFG process consulting | Validation | Site qualification | 250+ Associates |
| Supplier quality | 7 Customers | Supplier identification and qualification | 50 + Supplier site audit | | 30+ Associates |
| CAPA | 10 Customers | Process engineering CAPA | 50+ 483 based CAPA | 50 External audit CAPA | 60+ Associates |
| PMS + complaint handling | 10 Customers | 100+ PMS report | 60,000 complaint data | | 50+ Associates |

- **QMS remediation:** MDSAP, MDD, MDR, IVDR, ISO 13485, ISO 14971, 21 CFR Part 820, Part 11, GAMP, IEC 62304, CMMi L5
- **Manufacturing Process Consulting:** Six Sigma projects - process improvement, yield improvement, cost reduction
- **Validation:** Equipment validation, test method design, validation and transfer, process validation, computer system validation

# HCL Medical QMS

**MQMS – HCL's Medical Quality Management System - standard process framework addresses**

- **Design control processes –** Focus on design and development process such as design planning, design input, design output, design reviews, design verification, design transfer
- **Project management processes –** Focus on project management processes, such as from project initiation to closure
- **Integral processes –** Focus on integral processes such as configuration management, calibration, product risk management, training, internal audit, purchase etc.




**Deployment tools**

- Intranet-based system
- Process database

1. Risk / reusable components
2. Best practices
3. Learnings

**Deployment mechanism**

- Induction training
- Calendar-based training

1. MQMS training
2. ISO 13485, ISO 14971, IEC 62304 and QSR awareness training

- Role-based training – PQA, CC
- Process update training

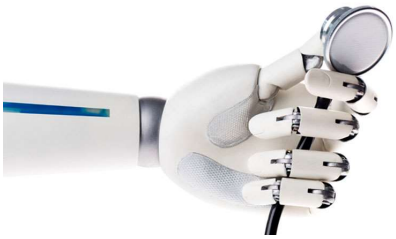
- ISO 13485 Medical Devices–QMS–Regulatory Requirement
- 21 CFR Part 820 US FDA Quality System Regulations (QSR)
- 21 CFR Part 11 Electronic Records; Electronic Signature
- ISO 14971 Risk Management for Medical Devices
- ISO/IEC 62304 Medical Device – SDLC Process
- IEC 62366 MD - Application of Usability Engineering
- AAMI TIR45 Guidance on the use of AGILE practices in the development of medical device software
- USFDA Guidance Documents for SW Validation
- MDD 93/42 European Council Directive for Medical Devices
- GAMP 5 (Good Automated Manufacturing Practice, by ISPE)
- GDP Good Documentation Practice
- ISO 9001 QMS – General Requirement
- MHLW Ministerial Ordinance No.169: Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents
- CMMI Capability Maturity Model integration (Ver 1.3) Level 5
- ISO/IEC 27001 Information Security Management System (ISMS)

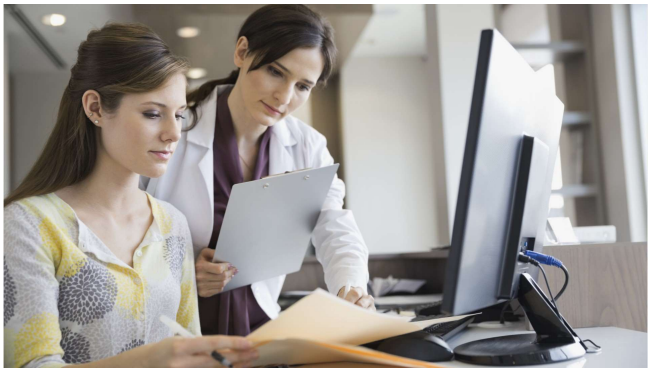
# Case study:

## Complaint management – Data analysis and trend analysis

### Project background:

Medical device customer was looking for someone who can review the complaint records of about 70,000 numbers and determine if the content has sufficient information to determine if this is a complaint or if additional information is needed to make a decision. Also, the person would need to review the adverse event survey completed by the complaint call center to determine if the survey appears to be completed correctly.





### Project scope:

To understand the customer complaint handling procedure and work closely with the PMS Team to evaluate the end customer product complaints, verify whether the adverse event survey is sufficiently aligned with the complaint text, review and bring it to closure.

### Accomplishments:

- Complete ownership of intake data which includes initiation, field, dispatch, and escalation to management
- Complete ownership on creation of quality notifications from investigation.
- Supporting the customer PMS team on the closure which includes (closed solved in field and waiting for approval).

### Stages

- Complaint evaluation and processing
- Daily reporting
- Quality notification creation
- Complaint allocation
- Tracking and trending
- Regional reporting
- Seamless communication
- Initiation
- Field dispatch
- Escalation to management

**60,000 + Complaints reviewed**

**40 + Complaints/day/head**

**100 + Quality notification creation**


# Case study:

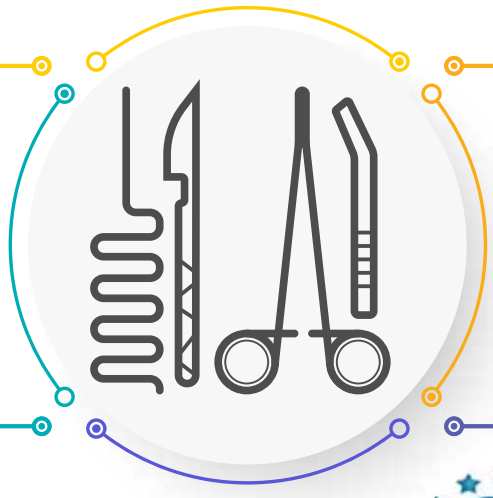
## CAPA for cleaning and sterilization of a reusable medical device

**Business statement:**

The USFDA audited the OEM and issued an inspectional observation (#483) for one of its reusable product. The OEM engaged HCL for analysis, CAPA proposal, and implementation.

FDA requirements for the reprocessing of reusable medical devices has been changed in March 2015

- HCL identified all the standards relevant to the reprocessing of the reusable medical devices globally
- HCL performed a gap analysis of all the all the IFU's against reprocessing related standards'
- HCL identified possible way of remediation of the gaps in reprocessing instructions
- HCL drafted the test protocols for sterilization of medical devices



## FOR MORE INFORMATION, PLEASE CONTACT

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