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HCL

Engineering partnership towards patient centric ecosystem

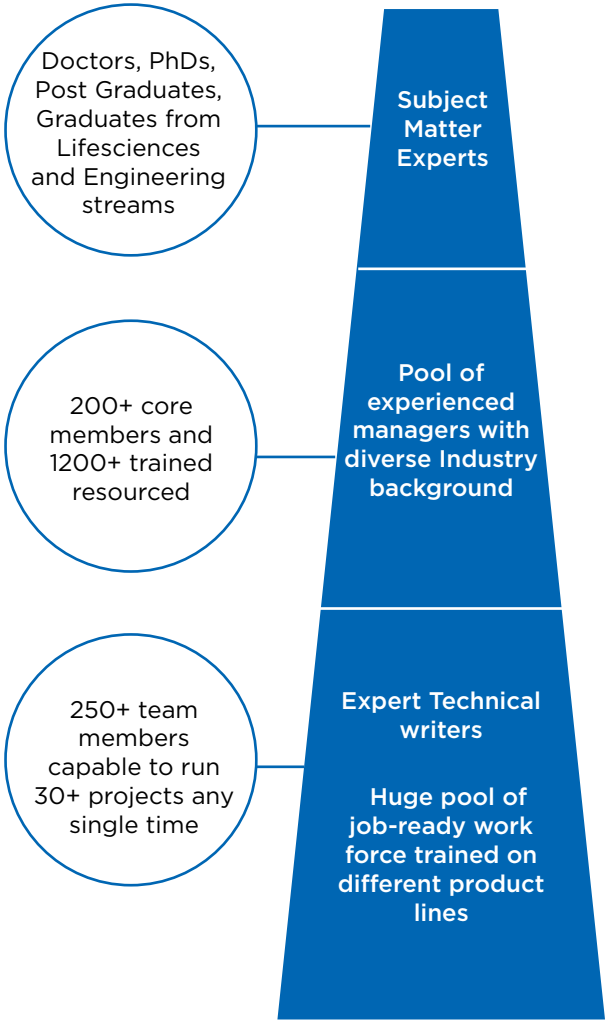
Acceleration | Compliance | Value

Regulatory affairs capabilities

With highly experienced 200+ **regulatory affairs** specialists and 1200+ trained resources, established relationship with notified bodies, experience in supporting remediation of QMS dor medical devices customers, and expert physicians within the clinical team, our Regulatory and Clinical CoEs bring in right domain expertise to provide simple and efficient approach to ensure **regulatory compliance** and quality.

HCL REGULATORY CENTRE OF EXCELLENCE

Values delivered



8 of 10 Top Medical Device firms and 4 of 5 Top IVD Device Firms

Interacting with 40+ Sites, working in 4 Geos, Multilingual like English, German, French, Japanese

7,000+ Tech Files supported for assessment and remediation

20+ QMS Assessment - Effectiveness Analysis and Remediation of procedures and templates

Process Maturity:
CMMI Level 5 | ISO:13485 | BS 7799 | ISO:27001

Successful support in implementation of process and product quality standards (e.g. ISO 13485, ISO 4971, ISO 60601x, ISO 10993, IEC 61010x, 61326x IEC 62304, IEC 62366x and UDI)

At every step of your regulatory affairs journey

Design for Compliance

- Regulatory requirement identification.
- Product-wise regulatory feasibility assessment.

Regulatory Scope Assessment

Regulatory Work Planning

- Risk-based classification
- Predicate device/ Reference identification
- Review of applicable Standards & Regulations
- Source File analysis and gap assessment.
- Review of clinical validation and safety testing requirements
- Pathway (Route) of Regulatory submission
- QC check mechanism

State of the Art

- Detailed gap assessment according to applicable standards
- Labelling design and content review.
- Remediation support

Regulatory Reviews

- Risk Management Files.
- CER and PER.
- DHF content.
- Promotional materials.
- Design Records.
- Batch Release and QC records.

Performance Evaluation assessment and remediation

- Co-ordinate with NRTL/Accredited test lab for Safety, **Regulatory Compliance**

Technical File preparation

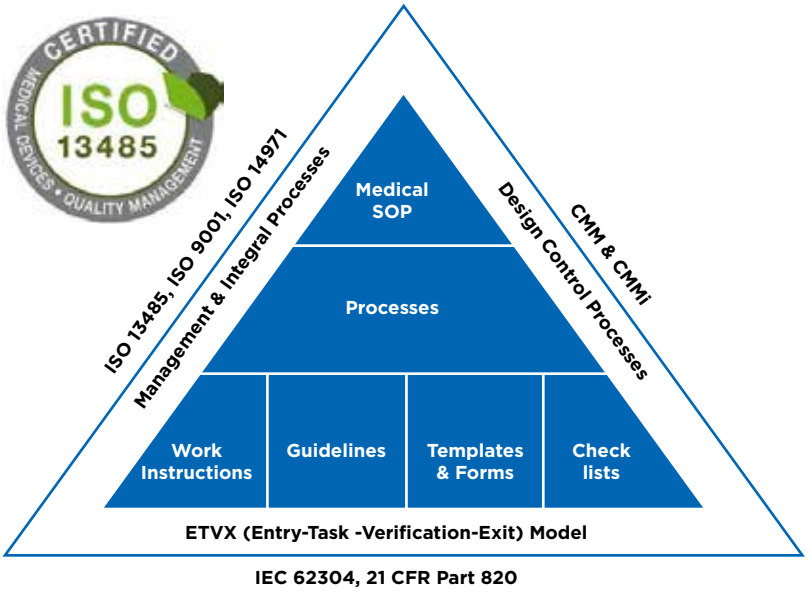
- Dossier/Technical file preparation according to accepted TOC.
- CE- Marking ownership.
- Support during onsite audit by the regulatory agencies or Notified Body

Post Approval Support

Design for Compliance

- Maintain Dossier/ Technical Files
- Track Standards & Regulations
- Change Impact Assessment
- Post-Market Incidence/event reporting.
- Complaint handling
- CAPA tracking and Tech File update

MQMS, our principle and approach



Deployment Tools

- Intranet based system
- Process database
  - Risk / Reusable components
  - Best Practices
  - Learning's

Deployment Mechanism

- Induction Training
- Calendar Based Trainings
  - MQMS Training
  - ISO 13485, ISO 14971, IEC 62304 & QSR awareness Trainings
- Role based Training – PQA, CC
- Process update Training

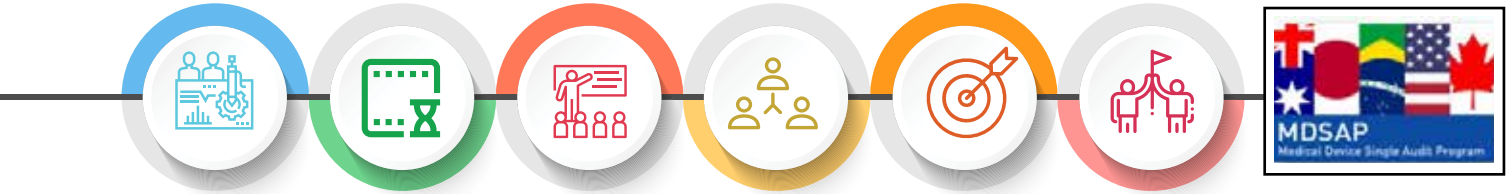
- **ISO 13485** Medical Devices–QMS–Regulatory Requirement
- **21 CFR Part 820** US FDA Quality System Regulations (QSR)
- **21 CFR Part 11** Electronic Records; Electronic Signature
- **ISO 14971** Risk Management for Medical Devices
- **ISO/IEC 62304** Medical Device – SDLC Process
- **IEC 62366 MD** - Application of Usability Engineering
- **AAMI TIR45** Guidance on the use of AGILE practices in the development of medical device software
- **USFDA** Guidance Documents
- **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:
QMS assessment and update for MDSAP

SCOPE
- Gap assessment and Remediation activities of MDSAP

TRAINING
- Train the internal task force team to understand the project details and regulatory requirements

CHALLENGES
- Understanding & working on MDSAP companion document requirement
- Traceability and understanding of client Process / SOPs



TASK FORCE & DURATION
- Total Team Size : 7 No's
- Gen Regulatory Lead (Offshore) : 2 No's
- Gen Regulatory Engineer (Offshore) : 5 No's
- Duration of the Project : 12 Weeks

TASK MANAGEMENT
- Preparation of process wise work sheet mapping with MDSAP requirement
- Collect the required inputs from client
- Conduct the gap assessment as per companion document (MDSAP) requirements
- Address & Remediate the Gaps Identified
- Review & Query Resolution

ACCOMPLISHMENT
- Early meeting of project timelines
- 100% QMS Coverage
- Customer Satisfaction

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 70K numbers and make determination if the content has sufficient info to determine if this is a complaint or if additional info is needed to make a decision. Also the person would need to review adverse event survey completed by 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, 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)

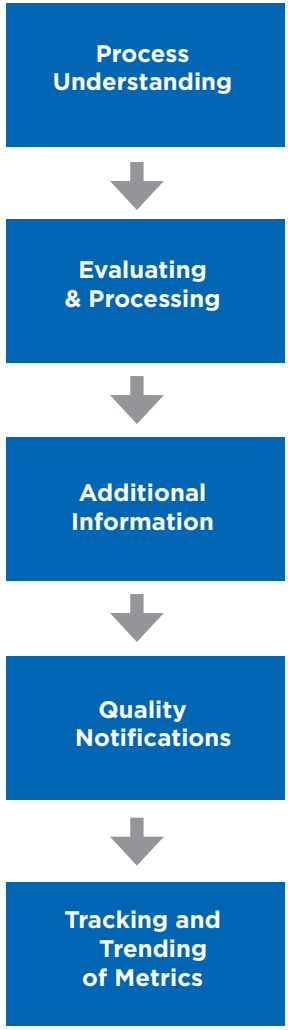
Stages:

- 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



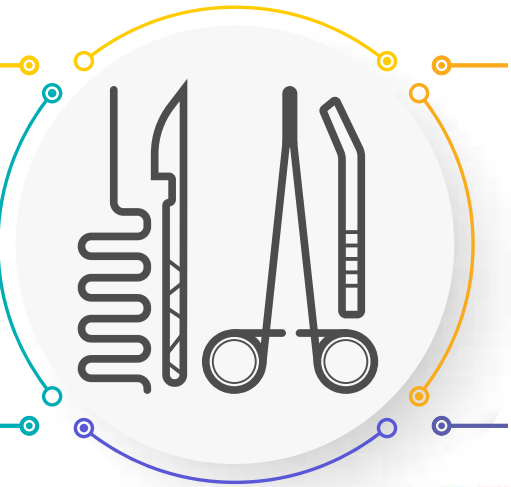
CASE STUDY:
CAPA for Cleaning and Sterilization of reusable Medical Device

Business Statement:

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

FDA requirements for the reprocessing of the 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 the all the IFU's against reprocessing related standard's
- HCL identified possible way of remediation of the gaps in reprocessing instructions
- HCL drafted the test protocols for sterilization of medical devices



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