www.hcltech.com

Growth partnership for a self-care centric lifestyle

Innovation | Acceleration | Growth

MDR
The countdown is on!
ARE YOU READY?

The new Medical Devices Regulation (MDR) brings several significant changes, putting on all medical device companies to closely examine the regulation, assess the impact it will have on their organization, and implement compliance processes and procedures accordingly. It is critical to swiftly go around devising new regulatory strategies to move forward efficiently and in time.

HCL - The answer to all your MDR needs

MDR COMPLIANCE CHALLENGES

INTERPRETATION & UNDERSTANDING REQUIREMENTS

- Only very limited Commission Guidance and templates available
- MDR harmonized standards list still not published so big confusion on state of art to be followed
- EUDAMED not available yet

PRIORITIZATION OF PRODUCTPORTFOLIO

- Product rationalization based on remediation cost
- Revamping strategies seeing COVID-19 impact leading to possible MDR delay

MASSIVE DOCUMENTATION AND LABELLING UPDATES

- Re-authoring of all technical files and clinical evaluation reports as per thelatest proposed structure
- Creation of new medical device safety documents such as Period Safety Update Report, Summary of Safety & Clinical Performance, Patient Leaflets etc.

READINESS & AVAILABILITY OF NOTIFIED BODIES

- Not all Notified Bodies will continue to operate under MDR
- Most MDR Notified Bodies will operate under a reduced scope

TRANSITION STRATEGY & TIMELINE

- Compliance is required by May 2020 with possible delays due to COVID-19
- Smart renewal of MDD certificate to extend product availability

MDR IMPACTS ALL AREAS OF THE BUSINESS

REGULATORY

- All Technical Files need to be updated to the new format, and need to include a Post Market Surveillance Plan
- Up-classification of several devices, including software
- Scope expanded to include devices without a medical purpose

R&D

- A design history file is required for all devices, including legacy devices
- Identification of hazardous substances in Medical Devices
- State of the art requires compliance to latest standards
- No grandfathering!

CLINICAL

- Clinical trial data required for class lll and implantable devices
- Post Market Clinical Follow Up Plan and Report required for all devices
- Summary of Safety and Clinical Performance required

LABELING

- All labels need update to include UDI, hazardous substances and Medical Device symbol
- New labelling requirements for primary packaging of sterile devices
- Implant card and Patient Leaflet are required for implantable devices
- Labels need to be published on a website and available in the local language

MEDICAL SAFETY

- Enforced post market surveillance with feedback into risk management and labelling
- Periodic Safety Update Reports to be published (bi) annually
- Post Market Surveillance Plan and Report required for all devices
- Implementation of trend reporting
- Timeline for reporting of adverse events reduced from 30 to 15 days

SUPPLY CHAIN

- The full supply chain has to be mapped out to identify the economic operators: Importer, Distributor, Authorized Representative
- Contracts need to be in place to ensure obligations of the different operators are met
- Master data for EUDAMED SKU registration (+/- 60 data points) need to be captured and maintained
- Person responsible for regulatory compliance to be identified at the manufacturer and the Authorized Representative

QMS

- QMS needs significant updates and require compliance to latest version of quality standard in ISO 13485, if not already done
- Planning & managing recertification audits

HCL HAS CAPABILITIES AND RESOURCES TO MEET YOUR NEEDS

REGULATORY

- 350+ member Regulatory CoE with average domain experience of 10+ years
- Experience across electromechanical & diagnostic space, disposables and implantable
- Working relationship with global Notified Bodies including TUV, UL, BSI…

CLINICAL

- Extensive medical writing staff with experience in literature searches and Clinical Evaluation Report writing
- Working with top 10 medical device companies for submissions in USA, Europe and Australia
- Extensive network of clinicians throughout India and USA supporting clinical assessment & reporting

ENGINEERING

- 43 years of engineering heritage, 20 in Medical Device Engineering space
- Co-created 170+ medical devices across class I, II and III

Quality

- Best in class Medical Quality Management Systems and Processes, compliant to ISO 13485, ISO 14971, IEC 62304, 21 CFR Part 820 and ISO 27001
- QMS Process Definition for 7 Medical Device manufacturers
- Ability to conduct independent QMS Audits

PEBLES

- Centre of Excellence in Packaging, Biocompatibility, Labelling & Sterilization and Post Market Surveillance (PMS CoE)
- Implemented UDI across 30000+ labels, executed 25000+ graphics/labels for line extension
- Partnership with external laboratories for biocompatibility & toxicology testing
- Tie up with labs to conduct reprocessing (cleaning and sterilization) validations for reusable devices
- Automated labeling and graphics design (software to modify the graphics, proof reading and verification)

HCL APPROACH FOR MDR TRANSITION PROGRAM

PHASE 1

Assessment

- Collect list of impacted products (Devices placed in EU Market)
- High level and detailed gap assessment for MDD to MDR compliance services

PHASE 2

Pilot & Planning

- Pilot remediation with limited number of representative Technical File
- Obtain Notified Body feedback
- Plan for implementation phase

PHASE 3

Remediation and CE Marking

- Implement the Remediation plan
- Update of QMS, DHF, TechFile including CER, labeling, RMF, DMR
- Creation of PSUR, PMSP, PMCF & SSCP
- Supply chain mapping and economic operators remediation
- Data gathering & submission to EUDAMED
- Hazardous substance identification, assessment & justification
- Review and approve changes
- Audit preparation and planning

PHASE 4

Lifecycle Management

- Maintain DHF, Technical File
- Post-market activities including PMS File, CER, PSUR updates
- EUDAMED data maintenance

HCL TYPICAL PROGRAM SETUP AND DELIVERABLES

PROJECT GOVERNANCE

Project planning, KPI reporting, transition planning
Management and coordination between workstreams

PROJECT WORKSTREAMS

Regulatory

- Tech file updates
- Gap Assessment
- Device up-classification
- Scope definition
- Basic UDI-DI strategy

R&D

- DHF
- General Safety and Performance updates
- Standards updates Compliance
- Hazardous substances assessment

Clinical

- Clinical Evaluation Report
- Post Market Clinical Follow Up Plan and Report
- Summary of Safety and Clinical Performance
- Literature searches for Clinical Data for legacy devices

Labeling

- Label assessment and updates
- UDI Implementation
- Creation of Patient Leaflet and Implant Card

Medical Safety

- Periodic Safety Update Reports
- Post Market Surveillance Plan and Report
- Trend reporting template and SOP
- Complaint handling process assessment and recommendations

Supply Chain

- Supply chain mapping
- Contract template for economic operators
- EUDAMED UDI master data identification
- RACI for Person Responsible for Regulatory Compliance

REGULATORY

- QMS assessment and SOP updates
- Notified Body recertification audit preparation and planning

HCL TOOLS AND TEMPLATES FOR SEAMLESS EXECUTION

CHECKLIST AND TEMPLATES

- Product classification checklist
- Labelling assessment checklist
- IFU assessment checklist
- UDI assessment checklist
- Checklist for Clinical Evaluation (CER) assessment
- Clinical equivalence checklist
- General Safety and Performance Requirements (GSPR) checklist
- Technical File checklist
- Risk management checklist
- PMS-Plan and report checklist
- Post Market Clinical Follow Up (PMCF) checklist
- Periodic Safety Update Report (PSUR) template
- Summary of Safety and Clinical Performance (SSCP) checklist
- Templates for plan and report (WIP)

RE-USABLE ASSETS GSPR LEVEL 1ASSESSMENT

- GSPR assessment completed for 30+
- Non-active implantable device
- Active implantable device
- Active Medical Device (Electro-Mechanical)
- Connected Medical Devices
- Re-usable surgical instrument
- Disposable Devices
- Mobile application (SaMD)
- Pre-Analytical Devices

FRAMEWORK FOR PRIORITIZATION

- Spreadsheet with weightage approach for product prioritization and recommendation

For more information please contact ERS.info@hcl.com

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 176,000 Ideapreneurs are in a Relationship Beyond the Contract™ with 500 customers in 50 countries. **How can I help you?**

BI-1032173127706694-EN00IN