Capgemini

Solutions for
Medical Devices

COMPLIANCE WITH THE NEW EU MDR AND IVDR

The need to strengthen the regulatory platform across the European Union (EU) is driven by the need to ensure patient safety and device performance. The new Medical Device Regulations (MDR) and In-Vitro Diagnostic Regulations (IVDR) regulations seek to harmonize the regulations to improve transparency and product traceability.

Medical and in-vitro diagnostic device manufacturers must meet strict deadlines over the next three years if they are to implement new compliance strategies without affecting the time to market of new products.

Regulatory changes are an effective step towards enabling the Intelligent Industry. Capgemini helps organizations transition smoothly to the new EU MDR/IVDR requirements by offering a customized strategic approach, from gap assessment to lifecycle management support.

What We Offer

Gap Analysis
- MDR gap analysis for the specific range of products
- Assistance with gap analysis of various harmonized standards and common specifications (not all of which are published yet) with the help of detailed checklists and tools

QMS Compliance
- Gap analysis of existing QMS with the new MDR and ISO 13485:2016 requirements
- Process redesign for compliance
- Mock audits for ISO 13485:2016 compliance
- Training and support on the new processes

Clinical/ Performance Evaluation Support
- Support in PMCF/ PMPF planning
- PMPF/PMCF report generation
- Clinical/performance evaluation reports (scientific validity, analytical performance, and clinical performance)

Product V&V
- Rapid testing through automation and frameworks
- Evidence for all the verification and validation requirements

Project Management
- A strong program and project management office that can steer the program smoothly to acceptance

PMS Support
- End-to-end support for all post-market activities
- Data update in the EUDAMED
- Technology solutions to support the complaint or feedback handling system
- New enterprise-wide technical architecture that will enable automated solutions

Technical File Remediation
- Support in GSPR and common specifications, harmonized standards compliance
- Support in pre-market and post-market technical documentation
- Support in DHF/ technical dossier preparation in STED format
- Support during NB submission

Labelling
- Digital technical publication CoE for all labelling solutions
- Thorough gap analysis for labelling and UDI
- Remediation and new label creation
- Updation of eIFUs and other documentation, as required

Capgemini

Key MDR/IVDR Impact Areas

We have a thorough understanding of the impact of the new regulations. The COVID-19 pandemic has already pushed the MDR compliance timeline to May 2021.

- Lifecycle approach
- Scope and classification of the products
- More transparency via EUDAMED
- General Safety and Performance Requirements (GSPRs)
- Mandatory technical documentation compilation & updates
- Traceability via UDI and implant cards
- Economic operators' responsibility
- More rigor to the QMS by including post-market and risk-management activities
- Increased involvement by notified bodies
- Vigilance and post-market surveillance (PMS) and PSUR reports
- Increased requirements for clinical evaluation, PMCF, and clinical investigations
- Increased requirements for performanace evaluation, and PMPF
- Increased clinical evidences reports requirement: scientific validity, analytical performance, clinical performance

Capgemini's Integrated Regulatory Framework (CIFR)

1 **Regulatory and Business Strategy: Understand the regulatory vision**

- Study portfolio of products and assess against the new regulations and future requirements including changes to classification, if any
- Depending upon the need for remediation, plan a business strategy, including necessary resources, training, budget, etc.

2 **Gap Assessment: Review and MDR gap assessment of portfolio**

- Get access to the existing QMS and documentation
- Identify the gaps to be filled (Review each annexure and the article to achieve complete coverage)
- Prepare a gap-assessment report and a remediation plan

3 **Remediation and Change management approach: Define MDR remediation strategy and execute strategy for end-to-end compliance**

- Implement the plan as per the gaps found. If the gap identification is thorough, implementing the changes for remediation becomes a fairly smooth exercise
- Typically, a cross-functional team is required for the implementation
- Notified body submission

4 **Lifecycle Management Support: Execute strategy for post-market MDR compliance**

- Plan proactive and reactive ways of gathering feedback, once the device is placed on the market
- Perform PMS, PMCF/ PMPF, trend analysis, etc.
- Implement a complaint-handling system that captures all the feedback, sorts it in various categories, and then transfer it as appropriate to be fixed

Credentials

✓ 18+ years of experience in engineering services for healthcare industry engaging with 65+ medical device companies

✓ Experience in 30+ clinical categories

✓ Experience of working with invasive and active medical devices

✓ Dedicated labelling and artwork team

✓ Enable digital transformation and provide solutions to address the changing needs of a connected healthcare ecosystem

✓ Process frameworks with detailed checklists available for every annexure

Our Expertise

- Deep medical domain focus and expertise in multiple product categories with dedicated regulatory teams for different regions
- Engineering projects for several Class II and Class III medical devices with the rigor of ISO-13485:2016 QMS, harmonized with ISO 14971 and IEC 62304
- Product and clinical workflow knowledge with in-depth understanding of QMS and SOPs
- Helping clients comply with various standards, guidance, and directives (IEC 60601, IEC 62366, ISO 15223, etc.)
- Understanding of GSPRs, technical documentation requirements, and their interpretation for various class devices.
- Experience in technical file and DHF remediation
- Leveraging technological advances such as IoT, analytics, AI, ML, complex event processing, cloud, mobility-based solutions

For more information, contact:
marketing.dems.global@capgemini.com