Quality Assurance and Regulatory Affairs for Medical Devices

The healthcare industry was the first to be significantly regulated in the modern era. With the advent of new technologies disrupting the ecosystem, healthcare industry is leveraging the opportunities which are poised to improve the quality of life. With the rapid changes taking place in medical technologies the regulations and quality requirements also need to keep pace and address the specific needs across different geographies. For Medical Devices, the regulatory compliance requirements kick in and play a crucial role from the product design phase and provide guidelines across the product lifecycle.

Capgemini helps organizations to adhere to the stringent norms under the product regulations to stay relevant in the market. With over 2 decades of product engineering experience, Capgemini has defined its Quality Assurance and Regulatory Affairs (QARA) offering to ensure the products are designed and engineered to meet the compliance and performance requirements.

One significant change in the compliance requirements has been introduced in Europe. The erstwhile Medical Device Derivatives (MDD) has been transformed to Medical Device Regulations (MDR) under the European Union regulations and the timeline for the adopting the change is 2020. The timeline for adopting the changes In Vitro Diagnostics Regulations (IVDR) is the year 2022. Capgemini's QARA offering is ready to support the medical devices industry in achieving this compliance change effectively and ensure that medical device companies launch products under the new guidelines of the European Union.

Our experience on standards and regulations

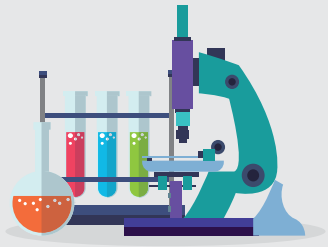
- ISO 13485, ISO 14971, IEC 62304, 21 CFR 820
- IEC 60601, 62366
- 21 CFR part 11
- 93/42/EEC, RoHS, MDR,
- IEC80001, HIPAA, ISO 27032, NIST framework

Capgemini's QARA Practice brings deep medical domain and multi geography regulatory knowledge base.

Integrated QARA Offering

- **Product compliance**
  - Design history file management (creation/remediation/ harmonization)
  - Product label/package design & implementation
- **Process compliance**
  - Quality system process assessment, audit & support
- **Technical documentation & reporting**
  - User manual, product catalog etc.
  - Regulatory data management & reporting
  - Clinical evaluation report & post market surveillance

17+ Years of Experience	Experience in **30+** Product Categories
Engaged with **6 of Top 10** Medical Companies	**ISO 13485** Compliant



Capgemini's Integrated Regulatory Framework (CIFR):

A Structured Approach to MDR Compliance

Understand Regulatory Vision vis-à-vis MDR & IVDR → **Review & Gap Assessment of Portfolio vis-à-vis MDR & IVDR** → **Define MDR/ IVDR Strategy and Roadmap** → **Execute Strategy for end-to-end MDR & IVDR Compliance**

Our MDR and IVDR Compliance Service Portfolio consists of:

- Device Re-classification - 'Essential Requirements' replaced by 'General Safety & Performance Requirements (GSPR)': Product Compliance & Remediation
- Technical Documentation - New Requirement : DHF Creation & Remediation
- Labelling and Unique Device Identification (UDI) – New Requirement: Product Labeling & Content Management
- Clinical Evaluation - More stringent clinical data requirements: Clinical Evaluation Reporting (CER)
- Post Market Surveillance (PMS) – More stringent requirements for PMS activities

Benefits to our customers:

- In depth knowledge and understanding of impacted areas in MDR
- Device classification change identification
- Reduced time to achieve compliance with templates for MDR impact assessment and process maps
- Partner ecosystem enabling product compliance and certification
- Documentation rigor with experience of over 200+ regulatory submissions supported

About Capgemini

A global leader in consulting, technology services and digital transformation, Capgemini is at the forefront of innovation to address the entire breadth of clients' opportunities in the evolving world of cloud, digital and platforms. Building on its strong 50-year heritage and deep industry-specific expertise, Capgemini enables organizations to realize their business ambitions through an array of services from strategy to operations. Capgemini is driven by the conviction that the business value of technology comes from and through people. It is a multicultural company of 200,000 team members in over 40 countries. The Group reported 2017 global revenues of EUR 12.8 billion.

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www.capgemini.com

About Capgemini's Product and Engineering Services (P&ES)

Capgemini's Product and Engineering Services (P&ES) brings together deep domain and technology expertise for both the digital and the physical world of products. Consulting, technology and assets led solutions enable global companies to unlock the true potential of their product portfolios. A recognized leader, with over 10,000 engineers across the globe and 30+ years of experience, P&ES offers a highly differentiated, comprehensive portfolio of services and solutions to meet the needs of digital engineering in a connected world.

People matter, results count.