Solutions for

Medical Devices

QUALITY ASSURANCE AND REGULATORY AFFAIRS

With the rapid changes taking place in medical technologies, regulations and quality requirements 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 adhere to the stringent norms set forth in the product regulations so they can stay relevant in the market. With over two 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 compliance and performance requirements.

WHAT WE OFFER

Our integrated QARA offering

Product compliance

- Design history file management (creation/remediation/ harmonization)
- Product label/ package design and implementation

Process compliance

- Quality system process assessment, audit, and support

Technical documentation and reporting

- User manual, product catalog
- Regulatory data management and reporting
- Clinical evaluation report and post market surveillance

OUR EXPERTISE

- **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
- **STRUCTURED APPROACH TO MDR COMPLIANCE**
  - Understand regulatory vision for MDR and IVDR
  - Review and gap assessment of portfolio of MDR & IVDR
  - Define MDR/IVDR strategy and roadmap
  - Execute strategy for end-to-end MDR and IVDR compliance

INSIGHTS & INNOVATIONS
for an *Intelligent Industry*

- Capgemini's QARA practice brings deep medical domain and multi-geography regulatory knowledge base
- Reduced time to achieve compliance with templates for MDR impact assessment and process maps
- Capgemini's Integrated Regulatory Framework (CIFR)

SUCCESS STORY

Partnered with an up-classified medical device manufacturer for complete engineering and product remediation of an endoscopy flushing aid device following the client design control process to comply with the regulatory requirements.

OUR ADDED VALUE

17+ years of **rich experience** to support the medical devices industry in achieving the compliance effectively

Advanced expertise with dedicated, strong team and **250+ regulatory submissions**

Vast experience in **30+ product categories**

Partner ecosystem enabling product compliance and certification

In-depth knowledge and **understanding** of impacted areas in MDR

Engagement with six of the top ten **Medical Companies**

For more information, contact:
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