Solutions for

Medical Devices

REMEDIATION SERVICES

Changing medical regulations around documentation needs, mergers and acquisitions, and product upgrades are leading to an increasing need for product remediation support services in the medical device industry. Companies need to ensure faster time to market of the product and be compliant to the demanding regulatory scrutiny.

To meet these challenges, Capgemini offers remediation services with our proven Rightshore® delivery model helping clients with 70% of remediation cost savings, 20% reduced time to market, and 10% productivity improvements leading to significant reduction in product lifecycle costs.

Capgemini with its industrialized approach to product remediation can support clients at an optimized cost and in a scalable, consistent, and transparent manner. Our trusted approach is built on key pillars of expertise in medical devices, system engineering, electro-mechanical disciplines, and specialization in regulatory affairs and quality management services.

WHAT WE OFFER

GAP ASSESSMENT

Detailed assessment of "As-Is' process and product documentation against new regulatory requirements, standards requirements, guidance documents and quality system processes for -

Safety and Performance

- General safety and performance requirements
- Applicable standards and solutions
- Common specifications

Technical Documentation

- Product documents (DHF/DMR)
- Technical files
- Declaration of conformity

IMPLEMENTATION OF REMEDIATION PLAN

- Review and compilations generated of product documentation as per regulatory requirement
- Design and development of documents
- Risk management file
- Usability engineering file
- Biological assessment document
- Cybersecurity assessment document
- Manufacturing information
- Applied standards List
- Safety and performance

Remediation services for

- EU MDR, IVDR
- M&A
- USFDA regulatory compliance

OUR EXPERTISE

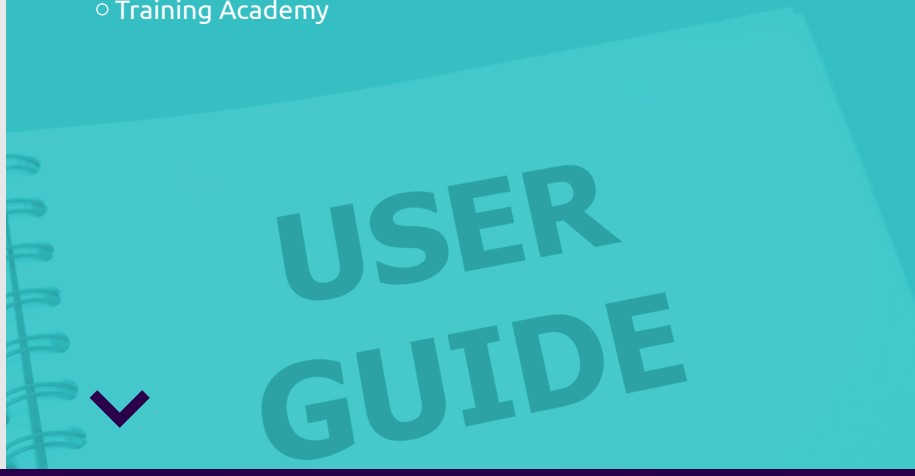
- **Experienced medical devices practice team for EU MDR and FDA compliance analysis and remediation**
- **Industrialized delivery with structured teams to ensure quick resolutions to compliance gaps and ensure reliable client outcomes**
- **Multidisciplinary skillsets such as hardware, mechanical and software, trained in medical regulatory landscape complemented with documentation capabilities such as IFUs, labeling and regulatory submissions all under a single window**
- **ISO 13485 certified quality management processes for medical device design and development with adherence to international regulatory guidelines and client specific standards**
- **Dedicated medical devices program management office for product and process compliance management**
- **Healthcare ecosystem partnerships with hospitals, doctors/clinicians, prototype manufacturers, test labs, external consultants**

INSIGHTS & INNOVATIONS

Our proven approach

- Capgemini's remediation approach is aligned to industry practices and comprehensive solution established through our engagement with leading clients and effective results.

- **Remediation CoE**
  - Quality Management
  - Labeling
  - System Engineering
  - Usability
  - Verification and Validation
  - Cybersecurity
  - Training Academy



SUCCESS STORY

Collaborated with a global medical devices company based in USA for creating DHF and DMR for successful compliance with the EU MDR requirements.

OUR ADDED VALUE

30+ years experience in engineering activities for highly regulated industry sectors including two decades on QARA services for medical device industry

10K+ experts deployed all over the globe (Europe, Asia, North America) in processes, methods and tools

Footprint covering **all strategic domains** (from engineering to manufacturing to customer services)

Wide portfolio with **tailored expertise** and solutions on tomorrow's technological challenges.

Rightshore® model of delivery with flexi scale up and out

Expert program management to handle end-to-end complex engagements with complete ownership

For more information, contact:
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