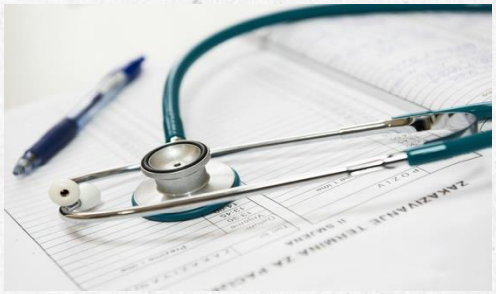
Medical Writing

- Intended Purpose, labeling, IFU
- Benefit-risk ratio
- CEP/CER, CDP
- PEP/PER, SOTA
- MDSW/ SaMD
- MDAI
- PMSP/R, PSUR
- PMCF/PMPF,
- SSCP



Clinical Services

- Clinical strategy
- Feasibility
- Study design
- Ethics
- Authority submissions
- Data verification
- Progress reports

Approval & Registration

- **CE Mark submissions**
- **FDA pre-submissions & submissions**
- Strategic review of technical documentation structure
- FDA meetings/communication
- Notified Body and NCA response resolution
- Completion of Notified Body application forms
- Manufacturer and Importer license
- Local device registration
- EUDAMED registration

Trainings

- EU MDR 2017/745
- EU IVDR 2017/746
- Trainings for ISO 13485 / 15189/ 14971 / 14155/ 20916
- Cybersecurity assessment
- Usability assessment

CMG edDeV

by Carmen Martín

From your idea to the patient

Your Regulatory, Quality and Clinical partner

Contact us

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Visit us at:
www.cmgmeddev.es

Who We are

CMG MedDev is a dedicated consulting service with more than **30 years of experience**, with a focus on the field of medical devices, in vitro diagnostics, software and MDAI.

Our Mission

We are focused on simplifying your journey by prioritizing product safety and efficiency, tailoring personal solutions that ensure the success of your projects from concept to market and beyond.

Our Team

Our team of experts collaborates closely with you to navigate the intricate landscape of MDR/IVDR, MDSW, MDAI, FDA, quality system and clinical research/studies.

Regulatory Services

- Device definition and classification services.
- Regulatory strategy development
- Technical documentation creation and review.
- Risk analysis according to ISO 14971.
- Implementation of **EU/FDA** regulations MDR, IVDR 510k, BDD, PMA, De Novo
- Implementation of standards like IEC 62304 for medical software.
- Test definition and validation services.
- Vigilance systems and post-market surveillance planning.
- PMCF and PMPF methodologies.
- Economic operator roles, UDI consulting, and EU MDR/IVDR consultation processes.

Quality Services

- Development and implementation of QMS according to ISO 13485, ISO 15189, ISO 17025, ISO 9001, GLP, GCP and GCLP.
- Implementation of QMSR (FDA)
- Conducting GAP analysis
- Development and implementation of documentation according to IEC 62304 for MDSW.
- Internal audits according to ISO 13485, ISO 17025, ISO 15189, GCP and GLP.
- Management of non-conformities and CAPAs.
- Liaison with NB and accrediting/certifying bodies.