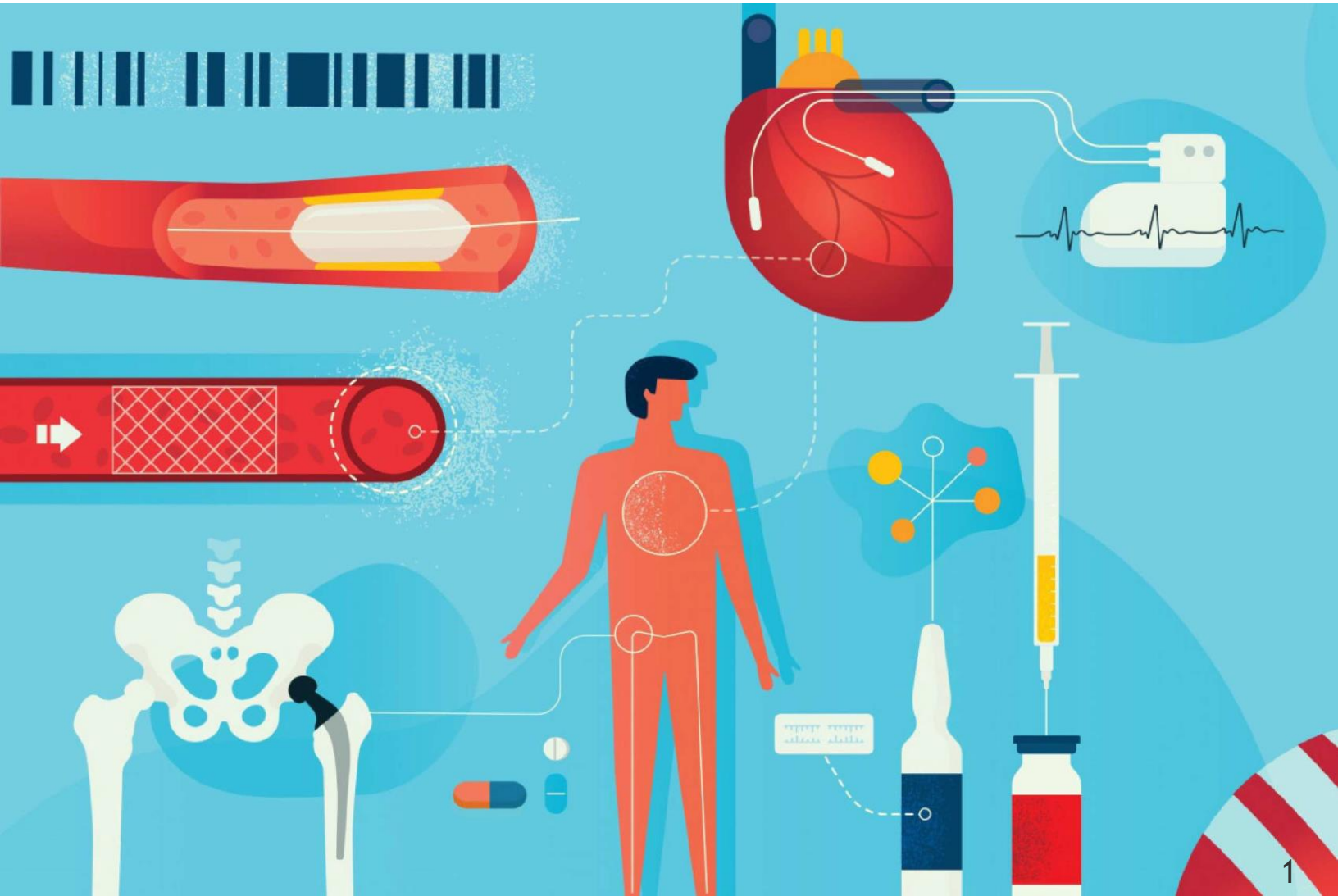
Why Choose GLOBAL?

A Proven Track Record in Medical Device and In-Vitro Diagnostic (IVD) Regulatory Consulting and Writing Services

GLOBAL | Regulatory Writing & Consulting



Why GLOBAL?

GLOBAL offers the highest quality medical device and in vitro diagnostic (IVD) device regulatory consulting and writing services to help your team gain and maintain market approvals worldwide. We have a team of regulatory professionals that got its start at the bench and in the clinical laboratory, with doctoral degrees and subject matter expertise in medicine, pharmacy, molecular biology, cancer biology, biochemistry, physiology, toxicology, and neuroscience. Using decades of cumulative experience, we help our clients develop customized regulatory, clinical, and post-market strategies to maintain compliance, while maximizing resource efficiency and minimizing challenges.

Regulation (EU) 2017/745 (MDR) and 2017/746 (IVDR) Specialization

GLOBAL's Medical Device & IVD Team specializes in Regulation (EU) 2017/745 (MDR) and 2017/746 (IVDR) and is comprised of over 20 US-based full-time subject matter experts. Our team began remediating EU technical documentation for MEDDEV Rev. 4 in 2015 and have been at the forefront of the MDR and IVDR transition. To this end, our team has an extensive history preparing regulatory technical files for submission under MDR and IVDR. Each year, we average over 100 successful projects related to EU CE marking, including new product submissions, annual updates, remediations, and regulatory responses and

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negotiations. We regularly help leading medical device manufacturers navigate the uncertain waters of MDR and IVDR as well as the unwritten expectations of the regulatory authorities and the notified bodies (NBs). Our experts will identify obstacles and provide clear and actionable recommendations, from detailed gap analyses and complex mitigation plans to managing and handling the remediation of your full portfolio.

Flexible Matrix Approach

We use a flexible matrix approach for resourcing and writing CER and PER deliverables, where all projects are managed by an experienced project manager and written by subject matter experts who are deeply familiar with the applicable regulations and most up to date guidance from the notified bodies. All work is completed in house and never outsourced, and you will have direct access to our writers to discuss your medical device or IVD device project as needed. All deliverables go through a rigorous internal quality control review to ensure that the conclusions are accurate and that the presentation is flawless. If provided, we will follow your templates, procedures, and style preferences. And if these do not exist, we are qualified to help you set up appropriate MDR/IVDR SOPs, WIs, and templates. It is for these reasons that GLOBAL has established itself as an industry leader and preferred vendor.

Experience & Proven Track Record

Our Medical Device & IVD Team currently works with several prominent medical device companies, most of which are repeat clients. We are experienced providing CE-marking support for an array of medical devices, from class III implantable devices to class I accessories. We are experienced in cardiovascular, neurological, pulmonological, urological, oncological, orthopedic, and ocular devices. We are also experienced providing CE-marking support for several unique IVD devices, including companion diagnostics, point-of-care devices, devices that are software, and accessory devices. Regardless of whether the device is considered a legacy device or a new product, we have the experience and expertise to support your submissions.

Our goal is to leverage our unparalleled breadth and depth of experience to ensure your medical and IVD devices gain and maintain market access. Bringing your next diagnostic innovation to patients everywhere, while ensuring it is safe and effective, is our priority.

Client Testimonials

Still not convinced? Then ask our clients why they keep returning to GLOBAL for their regulatory writing needs:

“First of all --- great job!!! I can't believe how well and quickly you understood and captured the topical area!”

“The project will be in GREAT hands under their team!”

“I want to thank you for the great support that you have provided to me and the team over the last three years. I would not have been able to do as much as I have done at [____] without you making my job as a CER project manager so easy. I hope to cross paths with you all again!”

“We received three certifications today on products that you worked on and wanted to thank you again for helping us get there.”

“Thank you for a very productive meeting. I appreciate your preparation and delivery, both of which should have instilled a high degree of confidence in the team.”