MARACA International is your partner for CE-Marking and FDA Submission of your products and delivers service excellence

Vision:

- Improving lives through service excellence

Mission:

- Providing best-in-class regulatory, quality and clinical services to medical device and in vitro diagnostic device manufacturers, clinical laboratories, pharma companies and notified bodies.

CEO Statement:

We are bringing as Partner more than 20 years' experience excellence for MD & IVDs to your company.

- The excellence of our people is our difference
- Clinical science is our expertise
- Your solutions are our focus.

Our promise:

- We'll point you to the gaps and deliver a high quality Design Dossier
- We'll be your ambassador with the Notified body and the FDA.

> "I have to tell you how impressed I'm with MARACA's services."

MARACA Services delivered by your CE & FDA expert

- CE-marking
- FDA Submissions
- Advise & Training
- Quality System: ISO 13485:2016
- Regulatory Systems: MDD, MDR, IVDD, IVDR, 21CFR820, MDSAP
- Clinical Evaluations (CER)
- Design Dossiers & STED
- Clinical Plans & Reports
- UDI & Labeling
- Audits
- Liaison with Notified Body & FDA

MARACA Advise and Training

To stay competitive in a quickly changing environment, with changing employees, regulations, standards and customer expectations, a company continuously needs training. MARACA International has established a series of training modules around the new European Medical Device Regulation, the European IVD Regulation, the US Medical Device regulations, the Quality System, ISO13485, ISO14971, GDPR, design control, risk management and technical documentation and conformity assessment.

Quality Systems

Why implement a quality system? The European MD and IVD Directives and MD and IVD Regulations include quality systems requirements. EN ISO13485:2012 is the harmonized standard for quality system requirements and ISO13485 certification provides a manufacturer several advantages. Moreover the new ISO13485:2016 should be implemented and satisfies also FDA Quality System requirements. MARACA can help you with advise, training and Quality System updating to the new ISO13485:2016.

Risk Management

The European Device Directives and Regulations, the US Device regulations and the China Device regulations require risk management as part of product development in the design dossier to authorize your products for distribution in their territories. A good risk analysis and evaluation is central to the development process and will be a valuable tool for troubleshooting and customer service.

MARACA INTERNATIONAL CONSULTING

EXCELLENCE AT YOUR SERVICE

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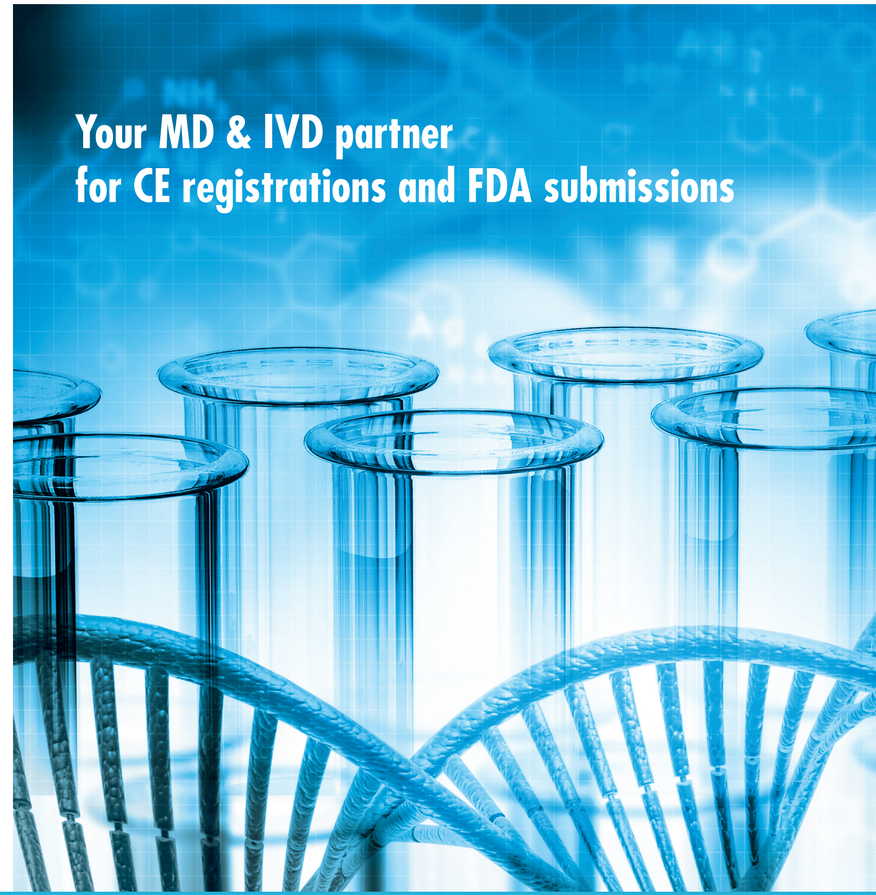
MARACA INTERNATIONAL

Your MD & IVD partner for CE registrations and FDA submissions



Unique service as medical Practitioner

- Design Review
- Risk-Benefit Summary
- Health Hazard Assessment
- Clinical Evaluation Report (CER)
- Clinical study protocols & reports
- Ambassador to NB & FDA

Our physician has more than 20 years' experience with developing medical devices. He'll translate customer feedback into your product requirements. He has lots of experience with developing risk management plans and reports using design and process FMEAs.

Our physician is uniquely placed to develop and approve the risk-benefit statement for your device based upon your risk management file and your Post Market Surveillance (PMS) data. When the product is on the market and an incident happens our physician can provide a Health Hazards Assessment immediately for impact of harm to the patient. As physician he is well versed in reviewing and summarizing literature for scientific validity and even more for clinical validity. He has the expertise to assess your clinical evaluation (CER/PER) report and approve it as Evaluator with inclusion of his CV and board certification. When more clinical studies are needed, he is best placed to develop a clinical investigation executive summary for further development by your clinical team. He'll approve your clinical study plans and reports as physician. Notified bodies (NB) and FDA are listening to his knowledgeable clinical defense of your product. Hence, you want him as your ambassador at your NB and FDA meetings.

> "MARACA is the greatest. Your senior consultant provides us the right level of regulatory service which we were lacking."

Performance Evaluations

- Scientific Validity Reports & Clinical Validity Reports with Lit. review
- Clinical Evaluation Reports (CER) with Lit. review & Gaps analysis
- Clinical Investigation Plans & Reports
- PMCFP

Europe, the USA and China require a Performance Evaluation of your products, including a systematic literature review.

MARACA can develop or assess your product Scientific Validity report and Clinical Validity report. We can run your systematic literature review and Adverse Events Databases (MAUDE and EUDAMED) review and develop or assess your Clinical Evaluation Report (CER) for Medical Devices and your Performance Evaluation Report (PER) for IVDs. As unique service we offer to sign the CER/PER report as Physician Evaluator with inclusion of CV and Board Certification. When the CER/PER identifies gaps and the need for a clinical investigation, we'll offer, as unique service, the development of an executive summary for the clinical investigation. This allows your clinical team to further produce the clinical study plan. We can approve the clinical plan and review the clinical study data to approve the clinical report.

When no clinical studies were performed in the past, we'll help you develop a Post-Market Clinical Follow-up Plan (PMCF Plan) and PMCF Evaluation report.

> "I have to write to say how pleased I'm with you being part of our team. I'm very impressed with your excellent support."

Regulatory Services for CE-Marking and FDA submission

- Full or partial management of your regulatory activities.
- General consulting and training on the new MDR and IVDR Regulations, the US 21CFR regulations and their impact on your business.
- Composition or review of your design dossier for NB assessment or third party FDA review.
- Review of your IFU and product labels. Advise in the design of labeling and Unique Device Identifier (UDI).
- Gap analysis of your quality system versus the requirements of the MDD/MDR or IVDD/IVDR Regulation, or the 21CFR 820 and ISO13485.
- Advice in the classification of medical devices, IVDs, software and health applications.
- Composition of performance evaluation plans and reports.
- Organization of clinical performance evaluation studies.
- Your ambassador with NB, CA, FDA, CFDA interactions and submissions.
- Management of incidents: Health hazard assessment, incident notification, recall and advisory notices.

Medical devices or in vitro diagnostic (IVD) devices placed on the European market, must meet the requirements of their respective Directives or Regulations. Conforming products receive the CE-mark label as evidence of compliance. Medical devices or IVD devices placed on the US market, must meet the requirements of their respective Code of Federal Regulations (CFRs). MARACA International offers a complete list of services to assist the manufacturer in obtaining the CE-mark and or FDA approval for his products.

Clients

Some past and current clients for regulatory, medical or clinical services:

JETA MOLECULAR · WILL PHARMA · gsk GlaxoSmithKline · BIOCARTIS · PAREXEL Right where you need us