Regulatory Affairs Medical Device

Navigate the changing regulatory landscapes with us

Regulation surrounding Medical Devices is changing faster and becoming more complex. We can support our Clients in the regulatory development process by providing customable and strategic services . We provide effective solutions to all to all the questions that arise when facing the set-up of a medical device. We can support you throughout all the step combining our quality skilled experts and the experience in this sector.

Pre-market **CE Marking** **Post-market**

GB Pharma group can assist you since the very beginning, helping you developing a complete project starting from your idea, checking the feasibility of your project, guiding you through the CE marking process, helping you with the increased request for clinical investigations and post-marketing clinical studies.

From the Idea to the project

We help our Clients facing early steps:

- Check of EU regulation
- Strategic consultancy on the project
- Feasibility of the project (costs, timing, requirements)
- Gap analysis of the document already available with respect to the Regulation
- Due diligence of technical files already existing

CE Marking

We help you by:

- Managing the certification procedure and contacts with the notified bodies and/or qualified laboratories;
- Checking of the technical file, writing and/or updating it (including clinical assessment, risk analysis, labels and/or instruction for the

OUR PLUS

- **High Client retention**
- **Multi-disciplinary team**
- **Clinical and non-clinical expertise**
- **A Regulatory Intelligence Network**

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user, Experts Reports, Overview, and Executive Summary Report).

Clinical Investigations

Clinical Investigations plays an important role on determining the safety of a medical device. Through our Clinical department we support you with:.

- Study Design and conduction;
- Clinical validation;
- Management of the clinical Investigations;
- Drafting of reports and conclusion;
- Inclusion of the results in the technical file.

Marketing and post-marketing

- Submission of medical devices and in vitro diagnostic medical devices notification to
- the Ministry of Health
- Revision of promotional material and submission to the competent authority
- Management of the national Medical Device database
- Medical Device post-marketing surveillance (PMS) according to EU Regulation
- Device-vigilance (support for the creation of a structure, maintenance and management, back-up)
- Request of FSC (free sale certificate)

Quality Management

- Support for creation of Quality Manual
- Support for SOP creation
- Support for upgrade to the latest ISO requirements
- Support for CAPA management
- Support for resolving Non Compliance of the system and/or the product
- Quality Management System maintenance
- Audits to the quality system
- Support for Audit for CE marking
- Support for ISO Audit

See more details for:

- Clinical Investigations with Medical Device

  learn more >

Contacts

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