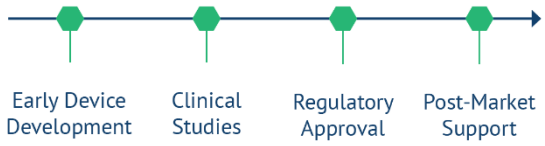
Clinical services for Medical Device

Our support to define a clinical strategy for the life-cycle of your Device

We provide Medical Device Manufacturers with a strategic and practical approach to perform Clinical Investigations for their Medical Devices. With the EU Regulations 2017/745, Regulatory Authority are demanding for more clinical evidence at both pre- and post- market level. We support our Clients in conducting:

- Clinical evaluation
- Conduct Clinical Investigations pre-market
- Clinical Investigations post-market;
- Post-market clinical FU studies;



We are able to provide support in all the life-cycle phases of a Medical Device by defining an effective strategy. We ensure compliance to the MDR 2017/745 and to the ISO 14155/GCP.

Our experts

Our dedicated Medical Device team is made of Regulatory and Clinical Experts with proven experience in managing the entire life-cycle of a Medical Device. We advise our Clients on the best clinical development strategy by defining tailored clinical investigations in order to speed-up time-to-market and to establish an effective post-market surveillance plan.

Clinical evaluation

A Clinical Evaluation is required for all medical devices. It is based on data generated from clinical investigations and/or literature reports related to device in question or a comparable device. Clinical data should be obtained prior the CE-marking and continuously updated. We support our Clients in the assessment of available clinical data and in the generations of new ones by defining an effective **clinical development strategy.**

OUR PLUS

- **Clinical experts**
- **Regulatory experts**
- **Pre- and post- market proven experience**
- **A global coverage**

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Clinical Investigations

The objective of a clinical investigations is to demonstrate the conformity with claims, of the medical device within the scope of the intended use. We are able to fully manage clinical investigations with medical devices from Class I to Class III, as well as implantable devices. Below is a list of our services for Clinical Investigations:

- Project Management
- EC and CA submissions
- Study and Site Files
- Data Management
- Biostatistics
- Monitoring
- Project Management

Are clinical investigations mandatory?

As a general rule, clinical investigations should be performed for implantable and Class III devices, unless relying on existing data is sufficient for your device. For other devices are not mandatory, but you need to demonstrate the conformity of your device.

PMCF Studies

Post-market Clinical Follow-up Studies are designed to identify the potential for residual risks of a CE Marked Medical device. They may be mandatory or voluntary, and are usually aimed to confirm the safety and/or the clinical performance of your product. They should be outlined in your PMS (Post-Market Surveillance) Plan. We help our Clients to:

- Evaluate the need of a PMCF Study;
- Dealing and negotiate with your notified body;
- Define the study protocol;
- Conduct the PMCF Study.

Our experience

GB Pharma has experience with pharmaceuticals, medical devices and food supplements in almost all therapeutic areas. With a focus on Medical Device, our recent experience include the following areas:

- Cardiology
- Cardiovascular
- Neurology
- Gastroenterology.

Contacts

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