Medical Device

Breaking barriers to market entry? We will guide you.

Do you require CE mark certification of your medical device in Europe? Would preparation of FDA 510(k) clearance in the US be of interest? Is a clinical study required?

Our dedicated and experienced team based in Scandinavia and Germany will guide you through the different phases in your product development; from creating your quality system, device classification, creating documentation as well as conducting clinical studies and undertake health economic evaluations.

Don't hesitate to contact us for an informal meeting or other inquires.

people and plans

LINKMEDICAL.NO

Medical Device

LINK Medical offers a unique portfolio on medical device services for small start-up company's through to established organisations , that needs more capasity and resources. We can provide you with advise on your regulatory strategy and guide you within the national and international regulatory requirements in an ever-changing regulatory climate. Our extensive experience enables us to guide your product and significantly increase its chances to launch the market.

We can assist you irrespective of which phase you are in including setting up your initial Quality Management System (QMS). Our medical device team is knowledgeable and experienced in handling all classes of medical device or medical device-drug combination products. Our project management system ensures systematic undertaking of your project from inception to completion.

Post-marketing follow-up surveillance are being reinforced by the authorities. LINK Medical provide services related to regular updates of your clinical evaluation report including a literature search or conducting an additional clinical study.

Health economic evaluation

Performing a health economic evaluation is vital to understand your products market potential and it is recommended to start at an early stage of the products life cycle. Our health economics team can assist you by demonstrating the value of your product to payers.

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Our services

Medical device requirements

- European and national regulatory requirements
- Product/Risk Classification
- Guidance for regulatory processes
- Risk management

Quality Management System (QMS)

- Quality systems & Quality assurance

Documentation

- Create CE EU Technical File/Design Dossier
- Medical writing
- Review labeling and user documentation
- User-testing

Clinical

- Clinical evaluation report
- Clinical study documentation
- Data management
- Statistics