Regulatory Affairs

Get it right. First time.

Are you looking for professionals who keep track of the ever-changing legislation within your market? Are punctuality, flexibility and ability to comply with fast upcoming deadlines crucial drivers for your business? Do you need assistance in a broad range of regulatory services – from simple variations, renewals and translations to compiling of dossiers (e.g. MAA, IMPD) and development of regulatory strategies?

Our regulatory affairs department provides the experience, ability and integrity to support the development of your medicinal product or medical device.

people and plans

LINKMEDICAL.NO

Marketing Authorisation

Our regulatory staff are experts in liaising closely with authorities, specialists and customers. This is vital when it comes to achieving marketing authorisation. We assist you during the entire process with preparation, assembling, validation and submission of documentation. We also recommend the most appropriate application procedure – such as centralised, mutual recognition, decentralised or national – and the type of application – such as complete, bibliographic, generic, hybrid or traditional use.

POST-APPROVAL SUPPORT/MAINTENANCE WORK

You can safely leave all the post-approval/maintenance regulatory activities to us. These include:

- Product information texts
- Variations/Renewals
- Transfer of marketing authorisations
- Medical writing
- Proof-reading artwork
- Catalogue texts, such as Felleskatalogen and FASS

Regulatory Strategy

In the competitive pharmaceutical and medical environment, time to market is critical to a product's success. This is why our regulatory affairs activities play an important economic role for most of our clients. LINK Medical delivers the knowledge and the strategic planning you need to minimize time-to-market.

Our experienced senior regulatory associates contribute both strategically and scientifically from product concept to approval of the marketing authorisation, including:

- Regulatory advisory services
- Assessment of suitability of available documentation
- Establishing product development plans for the pharmaceutical development phase, the pre-clinical phase and/or the clinical phase
- Preparation of pre-submission meetings and scientific advice/protocol assistance
- Rx-to-OTC switch strategies

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