



Regulatory Affairs

*Regulatory Strategy • Catalogue texts • Translations
• Marketing Authorisation Applications • Marketing
Authorisation Maintenance • Outsourcing*



LINK provides a wide range of regulatory services related to human and veterinary medicinal products (including medicinal gases and herbal medicinal products), food supplements, cosmetic products and medical devices.

LINK's Regulatory Affairs staff have amassed several decades of experience from both the pharmaceutical industry and the competent authorities. Our regulatory services vary from small tasks such as simple variations, renewals and translations, to larger projects such as compiling of dossiers, IMPDs and regulatory strategies.

Marketing Authorisation

LINK assists in the preparation, assembly, validation and submission of Marketing Authorisation Applications. We help you choose the most appropriate application procedure (centralised, mutual recognition, decentralised, national) as well as the type of application e.g. complete or bibliographic, generic, hybrid and traditional use. During the application process we liaise with the competent authorities. LINK takes care of all the steps involved in maintaining Marketing Authorisations, e.g.,

- *Variations*
- *Transfer of Marketing Authorisations*
- *Renewals*
- *Periodic Safety Update Reports (PSURs)*
- *Updating Summary product information text*
- *User/readability testing of package leaflets*
- *Proof-reading artwork*
- *Catalogue texts e.g Felleskatalogen and FASS*

Regulatory Strategy

Regulatory knowledge and strategy planning are crucial for your product success. Our Senior Regulatory Affairs associates are experienced in drug development and validation of regulatory documents, and will advise you through the drug development phase, from the product concept to the issuing of the Marketing Authorisation.

- *Providing regulatory advisory services*
- *Assessing the suitability of your 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*

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Your flexible link of expertise