REGULATORY AFFAIRS

Local Presence and Expertise

Local and coordinated Nordic support through one single point of contact

Our LINK Regulatory team offers extensive expertise in Regulatory Affairs and Lifecycle Management for the pharmaceutical market.

With a strong knowledge of local regulations and guidelines, we are your trusted partner in the Nordic region, ensuring compliance with national requirements. We provide flexible, tailored solutions based on your needs, with consultants available for ad-hoc, project-based, and on-site support, both short- and long-term.

We are your link to regulatory excellence in the Nordics. **Let's connect!**

bd@linkmedical.eu

Your link to NORDIC REGULATORY and MARKETING COMPLIANCE services

LINK MEDICAL

Introducing Our Experts

Kristine holds a BSc in Pharmacy and is a licensed Pharmacist, with postgraduate studies in Applied Physiology, Clinical Anatomy and Pharmacology. With more than 25 years of experience in Regulatory Affairs across the pharmaceutical and medical device industries, she brings extensive expertise to the field. Her professional background also includes over 15 years of leadership experience gained through various management roles within the pharmaceutical industry and at the Swedish Medical Products Agency. Kristine is based at LINK Medical's office in Uppsala, Sweden.

Kristine Nygren, Director Regulatory, Sweden

Morten holds an MSc in Pharmacy. With more than 20 years of Regulatory experience from Global Pharma he has accumulated much knowledge about the Regulatory environment in Denmark and post-marketing lifecycle management. Product launches are also one of his specialties. He is a trusted partner, who will help customers to navigate the complex regulations with confidence and clarity. He is based at LINK Medical's office in Copenhagen, Denmark.

Morten Becker Gaardlykke, Director Regulatory, Denmark

Birgit holds a BSc in Pharmacy. With 25 years of experience in the Pharmaceutical and MedTech industries, she has developed broad expertise across many aspects of Regulatory Affairs and Marketing Compliance. A strong focus on Nordic collaboration, combined with a service-minded and solution-oriented approach, characterizes her way of working. Birgit is based at LINK Medical's office in Oslo, Norway.

Birgit Jensen, Group Manager Regulatory, Norway.

40+ **Regulatory experts**	**80+** **Clients**	**250+** **Ongoing projects**

When relevant, a dedicated Project Manager will ensure collaboration and alignment across the Nordics, e.g. for labelling documents and common Nordic packs.

Some of the services our Regulatory experts can support you with:

- Consultation and advice on national legislation and requirements
- Communication with National Competent Authorities
- Regulatory strategy and coordination of all product launch activities.
- Marketing authorization-applications and CE certification
- Scientific Advice
- Marketing compliance & promotional material
- Life Cycle Management, e.g;
  - Variation applications
  - Transfer of Marketing authorization
  - Product information translations and/or Quality control
  - Artwork/mock-ups
  - OTC-switch
  - Maintenance of local databases e.g., FASS, Felleskatalogen, DKMAnet, Farmalogg, Pharmaca Fennica, Vnr, LiiV,
  - Educational materials/aRMMs
  - DHPC letters

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