



# Nordic Regulatory Services. Local Presence and Expertise.

Full Regulatory Support in the Nordics  
with one single point of contact

We are one of the largest Regulatory teams in the Nordics offering flexible services and a wide range of expertise within Regulatory Affairs, Marketing Compliance, Quality Assurance, Pharmacovigilance/Safety and Market Access.

We have extensive knowledge of local regulations and guidelines for the pharmaceutical market across the Nordic region. LINK Medical delivers comprehensive services for market entry and life cycle management for your pharmaceutical and medical device products.

**Guiding your path to the Nordic market. Let's connect!**

[bd@linkmedical.com](mailto:bd@linkmedical.com)

# Meet Our Experts



**Kristine Nygren**  
*Director Regulatory*

Kristine holds a BSc in Pharmacy and is a licensed pharmacist, with postgraduate studies in Applied Physiology, Clinical Anatomy and Pharmacology. She has more than 25 years of experience in Regulatory Affairs across the pharmaceutical and medical device industries. She brings more than 15 years of leadership experience from various management roles within the pharmaceutical industry and at the Swedish Medical Products Agency. She is based at LINK Medical's office in Uppsala, Sweden.



**Tina Madsen**  
*Director QA Operations*

Tina holds a MSc in Pharmacy from the University of Copenhagen. She has more than 30 years of experience in the pharmaceutical industry. Working in quality assurance from early-phase development through to commercial manufacturing in both small biotech companies and global pharmaceutical organizations, as well as at the Norwegian Medicinal Products Agency. She has experience as both Qualified Person and Responsible Person. She is based at LINK Medical's office in Oslo, Norway.



**Berit Nautrup Andersen**  
*Director Safety*

Berit is a registered nurse and holds a MSc in Drug Development from the University of Copenhagen. She has more than 20 years of experience in pharmacovigilance, clinical safety, and quality systems. She has worked in both small and large pharmaceutical companies, as well as at the Danish Medicines Agency. Berit has served as a QPPV for several international companies. She is based at LINK Medical's office in Copenhagen, Denmark.

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**50+ Experts**      **100+ Clients**  
**330+ Ongoing Projects**

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## OUR NORDIC REGULATORY SERVICES:

- Consultation and expert advice on national legislation and specific requirements
- Communication with National Competent Authorities and Notified Bodies
- Regulatory strategy and coordination of all product launch activities
- Marketing Authorization applications, CE certification and variations
- Life cycle management, incl. translations and product information updates
- Nordic marketing compliance and medical review of promotional material
- Maintenance of local databases, e.g., DKMANet, FASS, Felleskatalogen
- Pricing, reimbursement, and Health Technology Assessment (HTA)
- Ensuring GDP compliance in all wholesale activities
- Setup and maintenance of a Quality Management System (QMS)
- Specific roles, e.g., Responsible Person (RP), Qualified Person (QP) for Pharmacovigilance (QPPV), Person Responsible for Regulatory Compliance (PRRC)
- Part- or Full pharmacovigilance/Safety services, including safety database
- Management of Medical Information Enquiries