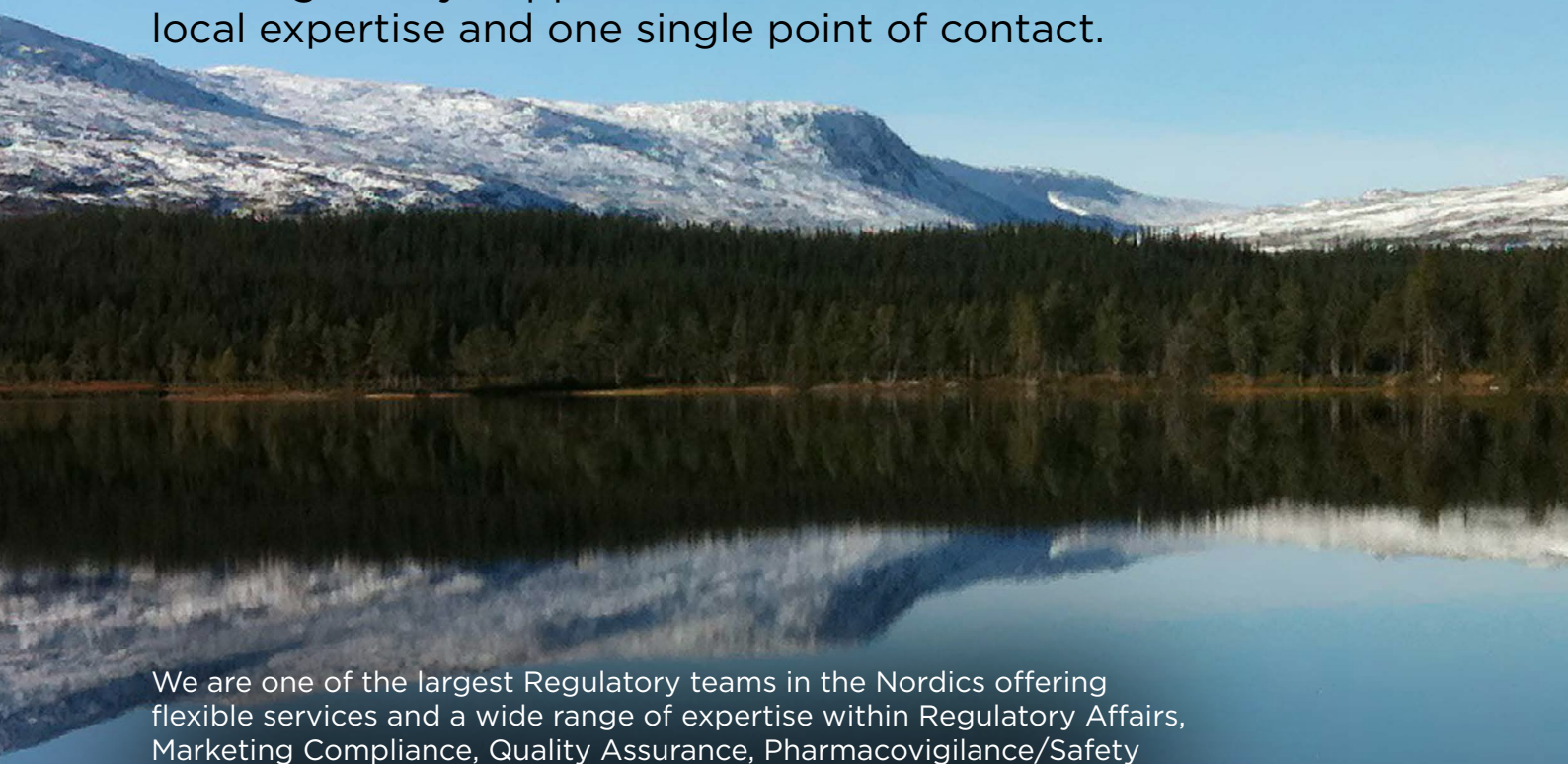
LINK MEDICAL

Regulatory affairs

Nordic Regulatory Services. Local Presence and Expertise. From a Trusted Partner.

Full Regulatory Support across the Nordics with local expertise and 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 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!

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LINKMEDICAL.EU

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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 27 years of experience in Regulatory Affairs across the pharmaceutical and medical device industries. She brings 17 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 Master of Science in Pharmacy from the University of Copenhagen. She has over 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. She has experience as both a Qualified Person and a 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 Master of Science in Drug Development from the University of Copenhagen. She has 24 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.

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

Our Nordic Regulatory Services to Ensure Compliance and Access:

- 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.
- Pricing, reimbursement, and Health Technology Assessment (HTA).
- Marketing Authorization applications, CE certification, and variations.
- Life cycle management, e.g., translations and product information updates.
- Nordic marketing compliance and medical review of promotional material.
- Maintenance of local databases, e.g., DKMAnet, FASS, Felleskatalogen.
- 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).
- Full pharmacovigilance services, including safety database and medical information support.
- Maintenance of local databases, e.g., Pharmaca Fennica, DKMAnet, FASS, Felleskatalogen.
- Specific roles, e.g., Responsible Person (RP), RP support, Qualified Person (QP).
- Full pharmacovigilance service support.