LINK MEDICAL

DRUG DEVELOPMENT

Regulatory Services for Drug Development

The Right Strategy

Smooth Approval

Developing a new drug or medicinal product?
Feeling overwhelmed by the complex regulatory requirements before clinical trials?
Let our regulatory experts guide you.

Our Nordic regulatory team at **LINK Medical** leads you through every step of early drug development. From CMC (Chemistry, Manufacturing & Controls) to non-clinical and clinical phases, we ensure your strategy aligns with current standards – minimizing risks and accelerating your path to first-in-human studies and beyond.

Let us simplify the process
— tell us about your regulatory needs today.

info@linkmedical.eu

Your LINK to // innovation & health

LINKMEDICAL.EU

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Meet the Team

Hilde Foros
Senior Regulatory Manager

Hilde holds a Master of Science in Biotechnology and has 25 years of experience in the pharmaceutical and biotech industry, the last 15 years as a CMC Regulatory Expert. She understands the requirements of the authorities and will pragmatically guide you in building and authoring a robust CMC strategy and documentation.

7 (Sr) Regulatory Experts

Each with decades of experience in the industry, academia, and regulatory authorities.

5 (Sr) Regulatory Experts

Holds a PhD from leading Nordic universities.

Why Partner with LINK Medical's Regulatory Experts?

- Regulatory strategy and guidance across **CMC, non-clinical**, and **clinical planning**.
- Support with **funding applications**, **due diligence**, and **target product profile workshops**.
- **Gap analysis** of existing documentation and preparation for scientific advice meetings.
- Expertise in **toxicology, pharmacology, PK/PD modeling**, and t**ranslational science**.
- **CMC advisory:** formulation, manufacturing processes, stability, and GMP readiness.
- **Preparation of key regulatory documents:** CTA/IMPD, IND, BLA, DMF, ASMF, CEP, MAA, NDA, etc.
- I**nterim and operational project management** with flexible insourcing solutions.
- **Local regulatory experts** with international experience.

Expertise & Therapeutic Areas (not exclusive):

- Non-clinical and Clinical Phase I–III development
- CMC: small molecules, biologics, radiopharmaceuticals, ATMPs
- Scientific advice / pre-IND
- Orphan drug designation
- Rare disease
- Oncology
- CNS
- And more across diverse therapeutic areas