SAFETY OPERATIONS

Built for biotech. Designed to scale with you.

Trusted Safety & Pharmacovigilance Services

Biotech companies often operate with limited resources, tight timelines, and evolving needs. LINK Medical provides the Safety & Pharmacovigilance expertise, infrastructure, and oversight needed to maintain compliance, without the complexity of building a full in-house PV organization.

From clinical development through commercialization, our experienced safety professionals provide the operational support, validated safety database, and strategic oversight needed to maintain a compliant and effective pharmacovigilance system. With access to experienced QPPV expertise and scalable safety operations, you can focus on advancing your product while we help safeguard patient safety and regulatory compliance.

Your gateway to the market — let's connect!

bd@linkmedical.eu

Your link to SAFETY OPERATIONS support

LINK MEDICAL

Meet Our Experts

Berit is a registered nurse and holds an MSc in Drug Development from the University of Copenhagen. She has more than 25 years of experience in pharmacovigilance, clinical safety, and quality systems. She has worked at both small and large pharmaceutical companies, as well as at the Danish Medicines Agency. Berit has served as QPPV for several international companies. She is based at LINK Medical's office in Copenhagen, Denmark.

Berit Nautrup Andersen, Director Safety

Tina is a registered nurse with more than 12 years of experience in pharmacovigilance, clinical safety, and safety database administration. She has gained extensive operational expertise from both pharmaceutical companies and her work at LINK Medical since 2021, giving her a strong understanding of regulatory requirements and end-to-end pharmacovigilance processes. Tina has hands-on experience in case processing, medical coding, safety data management for clinical studies, and safety database administration, including HALOPV. Tina is based at LINK Medical's office in Copenhagen, Denmark.

Tina Bugge Klok, Senior Safety Manager

Martina holds an MSc and a PhD in Animal Physiology and brings five years of hands-on experience in pharmacovigilance and drug safety operations. She has solid expertise in post-marketing pharmacovigilance and is highly skilled in preparing complex regulatory and scientific documentation, including toxicology reports, PSURs, DSURs, and addendum reports. Her expertise spans both device vigilance and human medicinal products, enabling her to support clients across a broad range of safety and compliance needs. She is based at LINK Medical's office in Lund, Sweden.

Martina Holst, Safety Manager

60+ Active clients	10+ Experts	100+ Years of PV experience

Scalable pharmacovigilance support tailored to biotech:

What we offer:

- Set-up and maintenance of PV systems (EU & global)
- Acting QPPV / local PV contact
- Clinical trial and Post-marketing safety support
- Case processing and literature screening
- Aggregate reporting (DSUR, PSUR)
- Signal detection and risk management
- Safety database hosting and management (incl. HALOPV)
- Vendor oversight and audit readiness

Why link medical for biotech?

- Right-sized support: Start small and scale as your pipeline grows — no unnecessary overhead.
- Fast implementation: Get PV systems and processes in place quickly and efficiently.
- One partner, full coverage: From early clinical phases to commercialization.
- Cost-efficient outsourcing model: Avoid building and maintaining a full internal PV infrastructure.
- Nordic quality, global compliance: Strong QMS and up-to-date regulatory expertise ensure inspection readiness.

Visit us at **linkmedical.eu**

Follow us on **LinkedIn**

LINK MEDICAL