QUALITY ASSURANCE

Nordic Quality Assurance Support

Your LINK to local Quality Assurance solutions for biotech, pharma and wholesale distribution.

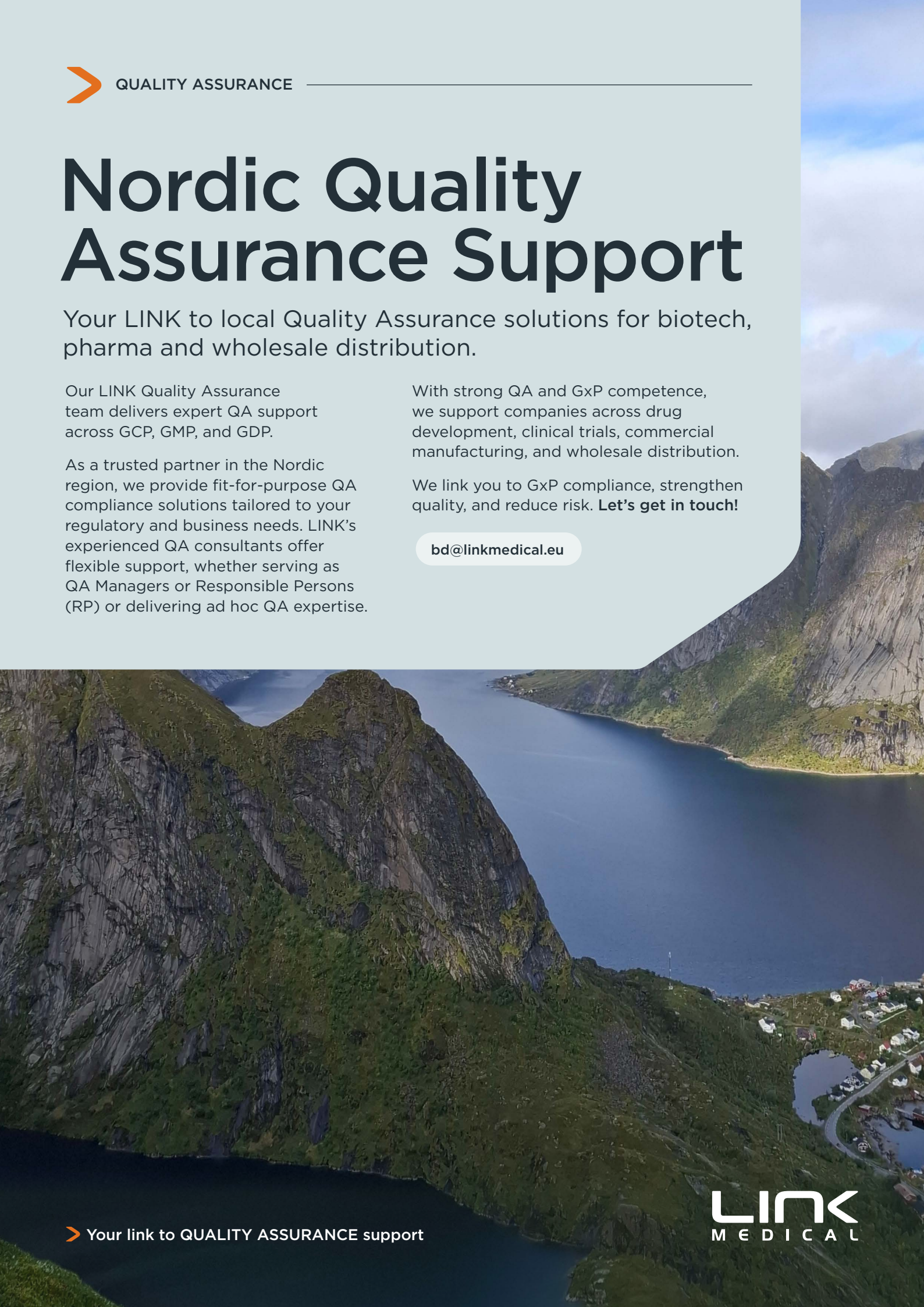
Our LINK Quality Assurance team delivers expert QA support across GCP, GMP, and GDP.

As a trusted partner in the Nordic region, we provide fit-for-purpose QA compliance solutions tailored to your regulatory and business needs. LINK's experienced QA consultants offer flexible support, whether serving as QA Managers or Responsible Persons (RP) or delivering ad hoc QA expertise.

With strong QA and GxP competence, we support companies across drug development, clinical trials, commercial manufacturing, and wholesale distribution.

We link you to GxP compliance, strengthen quality, and reduce risk. **Let's get in touch!**

bd@linkmedical.eu



Your link to QUALITY ASSURANCE support

LINK MEDICAL

Introducing Our Experts

Anna-Maria holds a Master of Science in Pharmacy and is a licensed pharmacist with more than 20 years of experience in the pharmaceutical industry. Her expertise spans commercial operations, regulatory affairs, pharmacovigilance, and Quality Assurance. She has extensive consulting experience supporting both small and large pharmaceutical companies and has held key roles as Senior QA and PV Manager, GDP Responsible Person, and Qualified Person for Pharmacovigilance (QPPV). Anna-Maria is based at LINK Medical's office in Uppsala, Sweden.

Anna-Maria Aulin, Sr QA Manager & Sr Safety Manager

Gro Helene holds a Master of Science in Biotechnology and has more than 15 years of experience in the biotechnology and pharmaceutical industries, working in compliance with international standards, including GMP, GDP, GCP, and ISO. Her Quality Assurance expertise spans early-phase GMP manufacturing, GCP clinical trial support, and commercial Quality Assurance, including GMP/GDP oversight and Responsible Person (RP) support. She has held key positions such as Senior QA Manager, Regulatory Manager, Head of Production (CMO), and Project Manager. In addition, she also brings key consulting experience supporting companies across a range of quality and compliance activities. Gro Helene is based at LINK Medical's office in Oslo, Norway.

Gro Helene Osnes, Sr QA Manager

Helena holds a Master of Pharmaceutical Science degree and has more than 20 years of experience in clinical trials, training, and quality management within the pharmaceutical industry. She has held several key clinical operations roles in both local and global settings, including Senior QA Manager, Quality and Training Manager, Senior Clinical Trial Manager, and Clinical Research Associate. Her expertise spans GCP, regulatory requirements for clinical trials, quality strategy, training, and inspection readiness. Helena brings key consulting experience in QA and GCP. She is based at LINK Medical's office in Stockholm, Sweden.

Helena Risinggård, Sr QA Manager

Explore our comprehensive range of Quality Assurance services:

QMS & Process Excellence – Establishing, maintaining, and improving Quality Management Systems (QMS):

- Establishment and optimization of fit-for-purpose QMS
- SOP development and document management
- Process improvement and gap analysis

Quality & Compliance Support – Operational and strategic QA support to ensure regulatory compliance:

- GMP and GCP, expertise across all clinical phases
- GMP and GDP expertise for pharmaceutical companies
- QA advisory and quality oversight
- Deviations, CAPAs, and compliance support
- Vendor qualification and quality agreements
- Regulatory intelligence / regulatory watch

Audit and Inspection Services – Independent assurance of quality systems and regulatory compliance:

- GxP audits across GCP, GMP, and GDP
- Audit program planning, execution, and follow-up
- Vendor, supplier and investigator site audits
- Internal audits services
- Inspection readiness support
- QMS GAP analysis

QA Expertise & Training – Flexible expertise and capability building:

- Outsourcing of GxP Quality Managers
- Responsible Person (RP) services
- Ad-hoc QA support
- Training in GxP and relevant regulatory requirements
- Regulatory intelligence / regulatory watch

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