*LINK Medical Research is an European, full-service contract research organization (CRO) that provides services within clinical trials, regulatory affairs, pharmacovigilance, health economics and quality assurance for the pharmaceutical industry and producers of medical devices. LINK Medical was established in 1995 and we are currently 98 employees based in Oslo, Stockholm, Copenhagen and Berlin. Our mission is to improve and accelerate our customers`product development.*

# Medical device expert in Stockholm

LINK Medical is experiencing increased demand for our services within medical devices and medical devices for in vitro diagnostics and therefore wants to strengthen the organization with a Senior Medical Device expert.

The position is placed in the department of Regulatory Affairs and Medical Device and geographically in Stockholm. It is desirable to have experiences from one or more of the areas described below.

## Responsibilities:

- Guide clients in implementation of quality systems according to ISO 13485 and FDA 21 CFR Part 820 (QSR) and conduct internal audits
- Participate in the development of Clinical Development plans and participate in the execution of clinical trials.
- Supervise and prepare documentation in accordance with European (CE marking, MDD / IVD) and US (FDA 510K / PMA) requirements for medical devices
- Guide clients in processes with Design Control and risk management for medical devices in accordance with international standards
- Prepare and revise Technical file / Design Dossier Documentation
- Develop clinical evaluation reports according to MEDDEV 2.7.1 revision 4
- Development, planning, participation and reporting in projects
- Contribute to the development of LINK Medical's business for regulatory services within medical devices
- Participate actively internally and externally to increase the level of knowledge in the field
- Customer contact, communication with customers in projects and contribute to further develop the company in collaboration with LINK Medical’s other employees

## Qualifications:

- Natural science degree at college/university level
- Knowledge and experience in regulatory affairs within medical devices / in vitro diagnostic
- Experience with companies having internal development and production of medical-technical products
- Practical experience in conducting quality audits
- Experience from clinical studies and assessments of usability
- Experience of project work is an advantage
- Generally good IT skills and use of standard office tools

- Service minded with good cooperation and communication skills, as well as oral and written presentation skills in Norwegian, English and preferably German
- Independent, flexible, accurate and solution-focused

## LINK Medical offer:

LINK Medical offers an exciting and challenging position in a European CRO that has a strong local presence. The company focus on collaboration, sharing of experience and continuous development. You will be given meaningful tasks requiring a good collaboration between industry, clinical and scientific teams and the authorities. We offer a competitive salary, pension and insurance scheme and a bonus scheme for all employees.

The position is located in Stockholm. If you have any questions about this position please contact Managing Director in LINK Medical, Sweden, Jan Hellqvist (+46 70 913 51 25)

**Please send your application and CV to;**
**Jan Hellqvist, jan@linkmedical.se before 30 of April**

All applications are treated confidentially.