LINK Medical Research is a 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 120 employees based in Oslo, Stockholm, Malmö, Copenhagen and Berlin. Our mission is to improve and accelerate our customers 'product development.

Regulatory Manager

LINK Medical Research LINK Medical Research is looking for highly motivated Regulatory Manager to join our Regulatory Group. You should have one to five years' experience from Regulatory Work with Pharmaceuticals and or Biotechnology Products. LINK Medical is growing and the portfolio of cross-functional projects is increasing. As a Regulatory Manager, you will work in close collaboration with members of several project teams and members of the Regulatory Group. You may also be outsourced to clients in a close proximity to your home.

Job Profile

Qualifications

- Basic education within relevant field, equivalent to degree from University or University College. Formal education may be compensated by experience
- Experience within Regulatory Affairs
- Preferably experience within Compliance and/or Pharmacovigilance
- Ability to show initiative
- Ability to work independently
- Knowledge about Pharmaceuticals and Biotech Products.
- Fluent in Swedish and English (written and oral)

Position Objectives

- Complete projects/services according to the agreement with project manager, line manager and customer
- Report progress of projects and other services according to agreement with project manager, line manager and customer
- Behaviour according to our promises (quality, punctuality, communication) and values (credibility, focus on solutions, job satisfaction)
- Contribute to the development of your area of expertise within LINK Medical
- Main responsibilities Completing task(s) according to applicable regulations, agreements and budget
- Ensuring that defined objectives and plans are met and complied to.
- Ensuring customers' positive perception of the collaboration with LINK Medical.
- Active project participation

Operation tasks may include but is not limited to:

- Regulatory submissions for approvals of new products, line-extensions; managing the preparation, content and format of the dossier, responding to authority questions for medicinal products.
- Driving submissions of variations and renewals
- Liaison with Health Authorities
- Preparation and maintenance of product information
- Review and approval of packaging materials
- Clinical trial applications
- Compliance tasks; review of promotional materials according to applicable legislations and guidelines
- Pharmacovigilance responsibilities
- Occasional Translations, Compliance and other tasks.

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 either Stockholm or Malmö. If you have any questions about this position please contact Managing Director in Sweden, Jan Hellqvist (+46709135125)

Please send your application to; Jan Hellqvist, jan@linkmedical.se