KLIFO
A step in the right direction

PHARMACO-VIGILANCE Services

Pharmacovigilance Specialist

KLIFO A/S is continuously expanding and is looking for experienced colleagues to join our Pharmacovigilance Team

KLIFO is an established and integrated drug development consultancy. We provide end-to-end expert capabilities, enabling our partners to maximise opportunity, mitigate risks, drive innovation and achieve efficient project advancement. We offer consulting and operational services spanning all areas of clinical research, pharmacovigilance, clinical trial supply, regulatory affairs, CMC development and the development of pharmaceutical and biotech products and medical devices.
KLIFO Pharmacovigilance Service offer flexible and effective solutions from early clinical development to marketed product support to meet our clients individual project needs.

Responsibilities:
We work with all aspects of drug safety and PV and the work involves collaboration and execution of projects according to our clients' needs and expectations.

Our services include:

- Set up of trial related activities (Safety Management Plans, Medical Monitoring Plans, Review and input to Protocols and other trial related document, Investigator's Brochure and Reference Safety Information) and Establishing and coordinating activities for Safety Committees and Data Monitoring Committees

- Safety handling in clinical trials (SAE handling and reporting - using Client's or KLIFO's Safety Database; Safety Surveillance and Signal Detection; Medical Monitoring; Coordinating and writing DSURs) and support of clinical submissions

- For established products: Case handling and reporting, using our Safety Database; Literature Monitoring; Writing aggregate reports; Answering Authority questions; support updates of labels/CCSI; Risk Management Plans; QPPV service

You will be involved in maintaining KLIFO's PV and Quality Systems, in cross-functional collaboration within KLIFO and you will support our Business Development.

Education, experiences, knowledge and skill:
We are looking for candidates with a MSc in the life sciences field or a background as a registered nurse having several years of experience from the pharmaceutical industry or biotech, working with Drug Safety/PV.

We expect that you are experienced with safety in the clinical trials setting and have good knowledge of GCP guidelines and clinical trial processes and are up-to-date with PV guidelines and legal requirements.

You are an experienced user of MS Office and has a good understanding of safety databases

You have a mindset with focus on high quality and the ability to prioritize different tasks in order to meet deadlines. You are a dedicated team player contributing to a good team spirit. Fluency, written and spoken, in English and a Scandinavian language, is a demand.

We offer:

- Work within different therapeutic areas and with a high variation in complexity
- Collaboration with a heterogeneous client pool (pharmaceutical, established as well as inexperienced biotech companies and also investigators/academia)
- An interactive and positive working environment

KLIFO is a smaller service provider, and we provide a high level of transparency, influence and an excellent opportunity for individual planning.

Location:
KLIFO is located at Smedeland 36, 2600 Glostrup.

Contact:
For more information, please contact Cathrina Karup, Director Pharmacovigilance Services at cathrina.karup@klifo.com or Lisbet Vandvig, Vice President, Clinical Trial Services at lisbet.vandvig@klifo.com

Applications should be sent to:
Malene.wirenfeldt@klifo.com

Deadline: 25 September, 2018

For more information on KLIFO, please visit:
www.klifo.com