

Experienced Regulatory Affairs Specialist

KLIFO A/S wants to engage an experienced Regulatory Affairs Specialist into a dynamic team working in the Regulatory Affairs Services business unit.

KLIFO is a service provider of drug development competences and operational services to pharmaceutical, biotech and med-tech companies in Europe, US and Asia. The services include Clinical Trial Supply, Clinical Trial Services, Pharmacovigilance, Regulatory Affairs and Drug Development Counselling.

The position:

The Regulatory Affairs Specialist is involved in or responsible for various regulatory activities for the customers of KLIFO, such as:

- Writing, compilation and submission of regulatory documents, e.g. (non-exhaustive list):
 - Briefing packages for Scientific Advice meetings with EMA, National Agencies, FDA
 - IMPDs
 - CTA/INDs
 - Orphan Drug Designation Applications
 - Paediatric Investigation Plans
 - Life Cycle Management activities
- Regulatory lead/Project Management
- Strategic advice
- Liaison with competent authorities
- Management of regulatory procedures
- Cross-functional collaboration within KLIFO
- Participation in cross-functional customer projects with other KLIFO business units

We want to engage a person who would like to work in a consulting environment, and has a positive, proactive, flexible and self-confident personality.

The qualifications:

The Regulatory Affairs Specialist must have a M.Sc. in the life sciences field or a RA specific diploma/master and a minimum of 8 years of experience within Regulatory Affairs from pharma, biotech or consultancy.

Solid knowledge of regulatory guidelines, terminology and processes is a necessity. The candidate must possess excellent communication skills (written and verbal), be fluent in the English language, be an experienced user of MS Office and have good understanding of databases. The job requires strong organizational skills with attention to details. The candidate will for some clients get an opportunity to work from the clients sites.

We offer:

KLIFO offers a job where you can:

- Use your regulatory skills and competences in a broad variety of regulatory activities covering development as well as life cycle management RA
- Work with a heterogeneous client pool (pharmaceutical companies, established biotech, small/virtual biotech)
- Build international client relations
- Excellent opportunity to interact with highly experienced colleagues within RA and cross-functional
- Work in an interactive and positive working environment

KLIFO is a service provider with a high level of transparency, influence and a potential for individual planning.

Location:

KLIFO is located at Smedeland 36, 2600 Glostrup.

Contact:

For more information, please contact Anne Tingsgård, VP Regulatory Affairs Services on +45 44 222 940.

Applications should be sent to:

Mette.widen@klifo.com

Deadline:

For more information on KLIFO, please visit:

www.klifo.com