CLINICAL OPERATIONS SOLUTIONS

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# KLIFO GmbH, Munich

## KLIFO is looking for a talented and committed
## Medical Writer

**KLIFO A/S** is a service provider of drug development competences and operational services to the pharmaceutical, biotech and med-tech companies in Europe, US and Asia. The areas covered by KLIFO include Clinical Trial Supply Solutions, Clinical Operations Solutions, Pharmacovigilance Solutions, Regulatory Affairs Solutions, CMC Development Solutions and Drug Development Counselling. KLIFO A/S has offices in Denmark, Sweden and Germany.

KLIFO now wants to appoint a talented and commited Medical Writer into a dynamic and experienced team within Clinical Operations Solutions. The people we want to engage like to work in a consulting environment and have a positive, proactive, flexible, self-driven and self-confident personality. We can offer a highly flexible, free and trustful working climate with exciting customers and projects among competent colleagues where your knowledge, experience and contribution are valuable and highly appreciated.

**The position as Medical Writer:**

The MW is responsible for creation of medical and scientific documents and the factual and formally correct display of scientific results and findings within clinical trials and non-interventional studies according to the FDA/EMA and ICH guidelines, i.e.:

- Writing of study protocols
- Generation of clinical study reports
- Generation of IBs and other documents related to the conduct of clinical trials, non-interventional studies according to the FDA/EMA and ICH guidelines
- Generation of patient facing documents, e.g. patient information
- Support the project team in preparation and compilation of narrative safety reports
- Advise the project team in preparation of study documents
- Prepare and give presentations when required
- Ad hoc tasks within the department and KLIFO
- Develop and review of SOPs to support department activities

**The qualifications of the Medical Writer:**

The Medical Writer should possess the following qualifications:

- MSc in the life sciences field or related discipline, preferable with a PhD and a minimum of 3 years in a similar position in the pharmaceutical industry/CRO
- Experience in Medical Writing, particularly in the creation of Clinical Study Protocols and Clinical Study Reports conforming to ICH-GCP
- Good statistical understanding in the area of descriptive statistics
- Ability to reproduce scientific data and complex issues accurately and in an understandable form
- Knowledge of SOPs, GCP guidelines, regulatory requirements, medical terminology and clinical trial processes
- Excellent Microsoft Office skills
- Excellent communication skills (written and verbal) in English as well as in German

In addition to the above-mentioned qualifications, the ideal candidate is action orientated, possesses good analytical skills, is able to make decisions and has strong planning and task management skills.

**We offer:**

- Work within different therapeutic areas and with tasks of varying complexity
- Work with a heterogeneous client pool (pharmaceutical companies, established biotech, inexperienced biotech, investigators/academia)
- Build international client relations
- Use - and elaborate - your competences and experience
- Work in an interactive, flexible and positive working environment

**Contact:**

For more information, please contact Doris Wiegel, Managing Director KLIFO GmbH at +49 89 895286-0.

**Applications should be sent to:**

job@klifo.com **before 21th August 2020, marked "Medical Writer"**

KLIFO processes your application and all related personal data exclusively for the specific hiring process. Your data is processed as confidential information, cf. the current data protection law (GDPR).

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KLIFO
An Integrated Drug Development Consultancy