CLINICAL OPERATIONS SOLUTIONS

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Medical Writer

KLIFO is looking for a talented Medical Writer in DK, SE or DE

KLIFO is expanding and wants to engage a Medical Writer into a dynamic and experienced team within Clinical Operations Solutions. The right candidate can be located in the Danish, Swedish or German office.

The person we want to engage strive to work in a consulting environment and has a positive, proactive, flexible and self-driven personality. We offer a highly flexible, free and trustful working climate with exciting customers and challenging projects among competent colleagues..

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 clinical study protocols
- Generation of clinical study reports
- Generation of IBs and other documents related to the conduct of clinical trials and non-interventional studies
- Generation of patient facing material, 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

Furthermore, the MW will generate or contribute to the generation of regulatory documents, i.e.:

- Briefing documents for authority meetings (primarily EMA, FDA and national EU authorities)
- Orphan Drug Designation Applications (EU and US)
- Paediatric Investigation Plans/Pediatric Study Plans (EU/US)
- General Investigational Plans (US)
- Fast Track Designation Requests (US)
- Break-through Designation Requests (US)
- Non-clinical and clinical overviews and summaries for Module 2 (IND, MAA, NDA and BLA)

The qualifications of the Medical Writer:
- 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/Clinical Study Reports conforming to ICH-GCP and writing of documents for EMA/FDA submissions
- 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 GCP guidelines, applicable regulatory requirements, medical terminology and clinical trial processes
- Ability to translate client's needs into writing
- Excellent communication skills (written and verbal) in English as well as in native language (if other than English)
- Microsoft Office Skills

We offer:
- Work within different therapeutic areas and with tasks of varying complexity
- 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

Location:
KLIFO has offices in Denmark, Germany, Sweden and The Netherlands. This position can be based in Denmark, Sweden or Germany.

Contact:
For more information, please contact Team Manager Stefan Ingelsson at +45 9189 4818 or Stefan.Ingelsson@klifo.com or Director Jennie Wilborgsson at +45 9363 8820 or Jennie.Wilborgsson@klifo.com.

Applications should be sent to:
job@klifo.com marked MW.
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).

Deadline: 31 May 2022 (although applications are reviewed on an ongoing basis).

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KLIFO
An Integrated Drug Development Consultancy

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Medical Writer

KLIFO is a leading integrated drug development consultancy with significant experience in partnering with biotech and pharmaceutical companies to advance their drug development projects. We provide end-to-end expert capabilities, enabling our partners to maximise opportunity, mitigate risks, drive innovation and achieve efficient project advancement. KLIFO has offices in Denmark, Sweden, Germany and the Netherlands and employs more than 150 highly skilled employees.

Join KLIFO and work together with some of the most experienced colleagues in the life-science industry. We have strengthened our competences over many years of dedication to our field of expertise, and we support and learn from each other. This gives us a positive, flexible and informal working environment and allows us to grow as individuals and as a company.
For more information visit KLIFO.com.

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