CLINICAL OPERATIONS SOLUTIONS

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Project Manager

KLIFO is looking for a talented and committed Project Manager Clinical Trials in Germany

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, Germany and The Netherlands.

The German office now wants to appoint a Project Manager for the conduct of clinical trials into a dynamic and experienced team within Clinical Operations Solutions in its Munich office. 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 Project Manager (PM):

The Project Manager is overall responsible for managing the clinical trials, i.e.:

- Main point of contact to sponsor representative
- Lead the clinical trial team and coordinate and manage all activities related to clinical trials
- Planning, delivery and management of clinical trial activities (start-up, operational conduct and closure) according to SOPs and a responsibility split with Sponsor
- Liaison with clinical trial team members regarding trial design and protocol preparation and ensure the production of the final trial protocol
- Lead the Risk Based Quality Management (RBQM) process including risk assessment and risk controls
- Development of project plans for the conduct of the clinical trial.
- Communicate timelines, identify milestones, handle trial budget and report progress for the clinical trials to sponsor and to COS management team
- Ad-hoc tasks within the department and KLIFO
- Develop and review of SOPs to support department activities
- Monitoring of selected sites, e.g. KoL
- When outsourced to a client and acting as Sponsor PM:
  - Carry out the CRO selection process and review CRO contracts with respects to tasks, budget and timelines
  - Lead the Sponsor oversight activities and ensure clear responsibility split between sponsor and CRO

Qualifications:

The Project Manager should possess the following qualifications:

- MSc in the life sciences field or a medical/veterinary degree and at least 5-6 years overall experience out of which 2 years in project management in the pharmaceutical industry/BioTech/CRO
- Extensive knowledge of GCP guidelines, applicable regulatory requirements, medical terminology and clinical trial processes
- Demonstrated project management skills including the ability to plan and conduct an international, multicountry clinical trial and operate within plan and budget
- Willingness to travel
- Excellent verbal and written communication skills
- Computer skills, ability to develop and maintain excel spreadsheets and to generate PowerPoint presentations.
- Fluent in English and in German (spoken and written)

The ideal candidate is a dedicated team player, 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

Location:

This position is located at our office in Munich.

Contact:

For more information, please contact Sibylle Gaupels, Team Manager Project Management & Data Management, KLIFO GmbH at +49 160 94143935

Applications should be sent to:

job@klifo.com marked Project Manager Clinical Trials, Munich.
Wir freuen uns auch über Bewerbungen auf Deutsch.

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).

KLIFO is an established and **integrated drug development consultancy** with offices in Denmark, Germany, Sweden and The Netherlands. We provide end-to-end expert capabilities enabling our partners to maximise opportunity, mitigate risks, drive innovation and achieve efficient project advancement. **For more information, visit KLIFO.com**

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