

## KLIFO is looking for a talented and committed eTMF Manager for our Glostrup Office

**KLIFO** is expanding our office in Denmark and wants to engage an eTMF Manager 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 eTMF Manager:

As eTMF manager in KLIFO you will be responsible for the continuous implementation and management of Veeva Vault eTMF and associated processes. The eTMF manager is responsible for setting up, maintaining, closing and archiving the electronic Trial Master File to ensure inspection readiness of the TMFs. The eTMF Manager is also responsible for providing comprehensive support to the clinical team for the set up and administration of projects conducted by KLIFO:

- Participate in client's kick-off meeting with the Clinical Team to align expectations on the TMF and related processes
- Prepare and adapt the Trial Master File index for Sponsor and Investigator files according to the specific study
- Create the study specific Filing Plan in alignment with the clinical team and the client
- Create and maintain standardized templates for eTMF components and other essential documents, based on best practices and KLIFO's procedures and in conjunction with Subject Matter Experts
- Plan and perform periodic TMF oversight activities to ensure Inspection Readiness at all times
- Ensure optimal use of eTMF functionality and industry best practices by transferring manual processes into automated workflows
- Participate in client's recurrent meetings to provide overview and status of the eTMF
- Create guides for the eTMF set-up, maintenance and closure according to the TMF Milestones.
- Create Essential Document Lists (EDLs), dashboards, reports and metrics acc. to the system, and ensure timely TMF quality control (QC)

### The qualifications of the eTMF Manager:

- Preferably a minimum of 2 years in a similar position in the pharmaceutical industry/CRO. Candidates within Business Administration, Librarian or equivalent will also be considered

- Knowledge of GCP guidelines, applicable regulatory requirements, medical terminology and clinical trial processes
- Understanding of regulatory requirements, guidances, and industry standards that govern TMF practices
- Experience in management and filing clinical trial documentation
- Ability to work in cross-functional teams
- Strong organizational, written and verbal communication skills
- Computer skills e.g. Microsoft Office Package
- Previous knowledge of Veeva Vault is an advantage

### 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:

KLIFO has offices in Denmark, Germany, Sweden and the Netherlands. This position will be located at our office in Glostrup, Denmark.

### Contact:

For more information, please contact Rejane P. De Pádua, Team Manager, at +45 54 581 863

### Applications should be sent to:

[job@klifo.com](mailto:job@klifo.com) marked eTMF Manager.

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:** 30 June 2021 (although applications are reviewed on an ongoing basis)

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](http://KLIFO.com)**