CLINICAL OPERATIONS SOLUTIONS

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eTMF Manager

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 also 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

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

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KLIFO
An Integrated Drug Development Consultancy

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

Contact:
For more information, please contact Jennie Wilborgsson, Clinical Research Director, at +45 93 63 88 20

Applications should be sent to:
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: 31 December 2021 (although applications are reviewed on an ongoing basis)

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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