REGULATORY AFFAIRS SOLUTIONS

REGULATORY AFFAIRS OFFICER KLIFO MUNICH

New established position as Regulatory Affairs Officer

KLIFO GmbH is currently expanding its service offering in Germany by introducing an end-to-end drug development consultancy including a Regulatory Affairs Solutions department, similar to what the company has in Denmark.

The Regulatory Affairs Officer is responsible for collaboration with clients as well as competent authorities and the execution of projects according to the clients´s expectations.

The position requires a hands-on approach to servicing existing and new clients in the DACH region.

You will report to our Senior Director New Business DACH in Munich with a dotted line to our VP Regulatory Affairs in Denmark.

The position as Regulatory Affairs Officer may involve:

- Project management
- Liaison with competent authorities
- General regulatory affairs work
- Management of regulatory procedures
- Preparation and submission of CTA as well as other regulatory documents, e.g. (non-exhaustive list): Briefing packages, IMPD, IND, MAA/NDA, Variations, Renewals, changes in the clinical trials, notification at the end of the clinical trials
- Writing and reviewing SOPs
- Cross-functional collaboration within KLIFO
- Participation in and support to projects in other KLIFO departments according to the training, experience and skills of the RA Officer

Qualifications:

- M.Sc. in the life sciences field or RA specific diploma/master and a minimum 2 years of experience within Regulatory Affairs in the area of clinical research in the pharmaceutical industry/CRO
- Excellent knowledge of regulatory requirements and ICH-GCP
- Excellent communication skills (written and verbal)
- Fluent in German and English
- Experienced user of Microsoft Office Package and good understanding of databases
- Strong organizational skills with attention to details
- Willingness to work from client sites, when required

In addition to the above-mentioned qualifications the ideal candidate is a dedicated and collaborative team player, possesses excellent planning skills and is fluent, spoken and written, in English and Danish.

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)
- Join a team of experienced colleagues where you use and elaborate your skills and competences
- Work in an interactive, flexible and positive working environment with a high level of transparency
- Opportunity to join an European-based organisation with global reach and a strong and dedicated plan for growth

Location:
KLIFO has offices in Denmark, Germany and Sweden. This position is located at our office at Heimeranstrasse 35 in Munich.

Contact:
For more information, please contact Senior Director Christine Tiesler at +49 89 8952 8631

Applications including salary expectations should be sent to:
job@klifo.com marked Regulatory Affairs Officer, Munich.

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 and Sweden. 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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KLIFO
An Integrated Drug Development Consultancy