REGULATORY AFFAIRS SOLUTIONS

SENIOR REGULATORY AFFAIRS SPECIALIST
KLIFO GmbH, Germany

KLIFO GmbH has an exciting opportunity for an enthusiastic and self-motivated individual to develop our regulatory affairs team in Munich, Germany

The position
KLIFO is an integrated drug development consultancy with headquarters in Denmark. In early 2019, KLIFO acquired medicomp GmbH, a Munich-based company providing life science services to pharmaceutical, medical device and biotech companies. The acquisition of medicomp is part of KLIFO's strategy to expand the company's operational footprint.

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

The Senior Regulatory Affairs Specialist will be responsible for building up and leading a Munich-based regulatory affairs team and supporting the establishment of new regulatory affairs business in Germany and the DACH region. In addition, the position requires a hands-on approach to service existing and new clients. The successful candidate will report to the Head of New Business in Munich and work in close collaboration with the Vice President, Regulatory Affairs Solutions from company headquarters in Denmark.

Functions as Regulatory Affairs Team Leader
- Identify and recruit candidates with solid regulatory affairs experience, in close collaboration with the HQ regulatory affairs team
- Provide leadership for the Munich-based regulatory affairs team as it grows
- Client liaison, project execution and oversight to ensure client satisfaction
- Develop the regulatory affairs business with current and potential DACH-based clients
- Promote KLIFO and its integrated drug development solutions offering by participating in conferences and other networking events etc

Functions as Senior Regulatory Affairs Specialist
- Project management
- Strategic advice
- Liaison with competent authorities
- General regulatory affairs work
- Management of regulatory procedures
- Preparation and submission of regulatory documents, e.g. (non-exhaustive list):
  - Briefing packages
  - IMPD
  - CTA/IND
  - ODD
  - PIP
  - MAA/BLA/NDA
- Project management and cross-functional collaboration within KLIFO
- Support to projects in other KLIFO departments
- Writing and reviewing of SOPs

Qualifications and requirements
- MSc from the life sciences field or Regulatory Affairs specific diploma/master and a minimum of 15 years' experience within Regulatory Affairs
- Profound knowledge of regulatory guidelines, terminology and processes
- Experience in liaison with Medicines agencies especially PEI and BfArM
- Broad knowledge of the key drug development steps
- Proven track record with good leadership skills
- Collaborative mind-set
- Personal fit with KLIFO's culture and way of working
- Extrovert service oriented (client-centric) mindset, preferably with experience from pharma and biotech as well as service provider side
- Able to work internationally
- Passion for developing the KLIFO regulatory affairs business provided out of the Munich office
- Network of regulatory experts in DACH
- Excellent communication skills, fluent in German and English (both written and verbal)
- Experienced user of MS Office and good understanding of databases
- Strong organisational skills with attention to details
- Willingness to work from client sites, when required
- Ability to travel for work (in Europe, up to 25%)

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 a European-based company with global reach
- Work in an interactive, flexible and positive working environment with a high-level of transparency and influence
- Flexibility to work partially home-based

The position is located at KLIFO GmbH, Heimeranstr. 35, Munich Germany.

Applications
Applications including salary expectations should be sent to:
Christine Tiesler, Head of New Business, KLIFO GmbH
christine.tiesler@klifo.com

For more information, visit www.klifo.com.

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