CMC DEVELOPMENT SOLUTIONS

CMC DEVELOPMENT SOLUTIONS
Senior CMC Expert/Project Manager

KLIFO is looking for a Senior CMC Expert/Project Manager for our Glostrup office

Would you like to use your CMC experience to support KLIFO's increasing number of biotech and pharma clients progressing their drug development projects?

Then a permanent position acting as a consultant as part of our CMC team might be just the job for you.

We're looking for a new colleague to become part of our highly experienced CMC team reporting to the Director of CMC Development Solutions (CDS).

We offer a unique opportunity to shape the content of the position and play a significant role in guiding and driving CMC development of a very broad range of international development projects and to deliver on specific CMC tasks. Our team develops tailormade CMC solutions ensuring that what we deliver to KLIFO clients is complementary to what the client can do by themselves.

Our professionalism is key and your new colleagues will be highly experienced within their field of competence.

You would become part of an international and growing company with an open-minded, flexible, sharing, and trustful working climate. We have a strong focus on and interest in people and work in a respectful informal culture. We're passionate about understanding our client's needs and objectives and contributing to their projects as if they were our own.

You will work closely together with colleagues in other KLIFO service areas and benefit from their vast experiences within clinical operations, clinical trial supply, regulatory affairs, QA etc.

For you to thrive and be successful in this role you

- Enjoy contributing to many different projects
- Manoeuvre respectfully and curiously in different company cultures and geographies
- Are pro-active and able to take the lead
- Have a collaborative mindset and are a flexible team player
- Communicate confidently in writing and verbally and in Danish and English - with attention to detail

Your tasks could be to

- Support and advice in drug development, including documentation (protocols, reports, recommendations, presentations)
- Develop and present CMC gap analyses, CMC strategies and plans
- Lead CMC teams and conduct CMC project management
- Identify CROs and CMOs and facilitate collaboration
- Draft, review or provide input to documents for correspondence with competent authorities (briefing package/scientific advice)
- Prepare or review documentation to support regulatory filing (module 2.3 and module 3, parts of IMPD/MMA, IND/NDA/BLA)
- Support upscaling, validation and transfer of manufacturing processes to CMO's
- Outline statistical design of experiments
- Plan and conduct CMC due diligence incl. reporting and recommendation

KLIFO A/S
Smedeland 36
DK-2600 Glostrup
Denmark
+45 44 222 900

KLIFO GmbH
Heimeranstr. 35
D-80339 München
Deutschland
+49 (0) 898 952 860

KLIFO AB
Medicon Village
Scheeletorget 1
223 81 Lund, Sweden
+46 709 135 125

KLIFO
An Integrated Drug Development Consultancy

Qualifications:

- M.Sc. (pharm.) or diploma in chemical engineering or equivalent
- +15 years drug development and CMC project management experience from pharma and/or biotech
- Particularly strong in CMC related to phase I to phase III clinical development
- Experience preparing regulatory documentation

Location:

KLIFO has offices in Denmark, Germany, Sweden and The Netherlands. This position is located at our office in Copenhagen, Denmark.
Most of us work partly from home and partly from the office or out of our client's offices.

Contact:

For more information, please contact VP Drug Development Counselling & CMC Development Solutions, Hanne Wulff Nielsen: Hanne.Nielsen@klifo.com, +4544222903
If you want to talk to one of your future CMC colleagues and learn more about their experience working in KLIFO then we're happy to arrange the contact.

Applications should be sent to:

job@klifo.com marked Senior CMC Expert.
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).
We review applications and invite for interviews 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