CMC DEVELOPMENT SOLUTIONS

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

Would you like to use your CMC experience in a permanent position acting as a consultant to support KLIFO's increasing number of biotech and pharma clients progressing their drug development projects?

We're looking for a new colleague to become part of our highly experienced CMC team reporting to VP Drug Development Counselling and CMC, Hanne Wulff Nielsen.

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 and how we do it is complementary to what the client can do by themselves. Our professionalism is key and your new colleagues would have 20-40 years experience within their field.

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

For you to thrive and be successful in this role you

- Enjoy to contribute to many different projects
- Maneuver 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 formulation 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 CRO's and CMO's and facilitate collaboration
- Draft, review or provide input to documents for correspondence with competent authorities (briefing package/scientific advice, IMPD, CTA/IND's)
- Prepare or review documentation to support regulatory
- filing (module 2.3 and module 3)
- 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

Qualifications:

M.Sc. (pharm.) or diploma in chemical engineering or equivalent
+15 years formulation development and CMC project management experience from pharma and/or biotech with either ATMP's, biologics or small molecules
Particularly strong in CMC related to phase I to phase III clinical development
Experience preparing regulatory documentation

Location:

KLIFO has offices in both 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 and CMC, Hanne Wulff Nielsen: hanne.nielsen@klifo.com, +45 44222903.
If you want to meet one of your future CMC-colleagues and learn more about their experience working in KLIFO then we're happy to arrange for that.

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 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**

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KLIFO
An Integrated Drug Development Consultancy