Senior CMC Expert

Join an international drug development consultancy and contribute with strategic advice and operational support to clients based in Europe, the US and Asia.

At KLIFO, you'll be part of a highly specialised team of experts who value workplace flexibility and collaborate to help our life-science clients across different therapeutic areas and stages of development realise their unique projects.

Become part of an experienced and dedicated team

We offer a unique opportunity to be part of a well-functioning team and play a significant role in guiding and driving CMC development of a broad range of international biotech and pharma development projects.

Our team of three senior CMC experts work closely together. We develop tailormade CMC solutions, manage projects and provide CMC advice for all types of drug substances and formulations in all stages of development.

In the role as Senior CMC Expert, you'll contribute by:

- Acting as the CMC expert within your field of expertise, e.g. analytical methods and characterisation, drug substance or drug product development and manufacturing processes. Ideally you have experience with small molecules and biologics and/or ATMP's
- Planning, leading and executing CMC activities
- Acting as the overall CMC expert on behalf of clients
- Identifying, screening, contracting and collaborating with CDMO's
- Preparing and reviewing internal documentation and documentation to support regulatory authority interaction and filing (briefing packages, module 2.3 and module 3, parts of IMPD/MMA, IND/NDA/BLA)

Location
Glostrup, Denmark

Employment
Full time or part time

Deadline for application
Applications will be assessed on an ongoing basis

Contact
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About KLIFO
- 150+ employees
- Offices in Denmark, Sweden, Germany and The Netherlands
- Headquarter in Glostrup, Denmark

KLIFO is a leading North-European drug development consultancy with significant experience in partnering with biotech and pharmaceutical companies.

We provide end to end solutions and support our clients with strategic advice and operational support across therapeutic areas and disciplines.

Your background and qualifications

You are an open-minded, responsible and pro-active team player who also enjoys to work independently with attention to quality and detail and the overall project objectives.

Furthermore, you:

- Are curious and have a desire to work with a diverse and dynamic range of clients and projects on smaller and larger assignments
- Have a keen interest in understanding the needs of our clients and how we can support
- Have a M.Sc. (pharm.) or diploma in chemical engineering or equivalent
- Have +15 years drug development and CMC project management experience from pharma and/or biotech
- Are particularly strong in CMC related to phase I to phase III clinical development
- Have experience preparing regulatory documentation
- Are fluent in English and Danish or Swedish, both written and spoken

Why join KLIFO?

- Join an organisation where we value people and their expertise as the greatest asset
- Enter a flexible workplace with a culture based on trust, transparency and respect
- Work with some of the most experienced and dedicated colleagues in the life-science industry
- Contribute with your expertise across different therapeutic areas
- Develop tailor-made solutions based on cross-disciplinary collaboration
- Cultivate successful relationships with our clients
- Be part of an organisation that sees knowledge-sharing as the road to success

Share your application

Apply by sharing your CV and motivation with us at job@klifo.com marked Senior CMC Expert as soon as possible. Kindly state how you heard about this position. Interviews will be carried out continuously.

If you have questions about the position, please reach out to Hanne Wulff Nielsen at hanne.nielsen@klifo.com or +45 44222993 for more information.

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).

For information on KLIFO's processing of personal information see https://klifo.com/disclaimer-privacy-policy/.

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KLIFO
An Integrated Drug Development Consultancy