CMC Specialist at VarmX BV

Are you a highly motivated individual interested in a position as CMC Specialist with broad responsibility in a small, entrepreneurial biotech company?

Our CMC team is currently looking for a highly motivated and enthusiastic colleague to support our Process Development and Manufacturing efforts directed towards supporting the company's preclinical and clinical drug development pipeline.

As we are in early phases of building the organization, we offer a highly dynamic job in a very interesting and continuously developing environment.

Within this role you will have ample opportunities to participate in the shaping the CMC organization and make significant contributions to your personal development as well as the future growth of the company.

Responsibilities

As CMC Specialist you will among others be responsible for:

- Support identification, selection and coordination of Contract Development & Manufacturing Organizations (CDMOs) for cGMP process optimization, manufacture, quality control, and supply of Biological Drug Substance and Drug Product
- Contribute to the further development of our Phase I/II manufacturing processes -upstream as well as downstream process steps
- In coordination with Quality Assurance, implement appropriate analytical methods and protocols and ensure that VarmX and all CDMOs are using systems and processes in compliance with relevant regulatory standards and cGMP
- Design and overview of project plans and protocols with internal and external stakeholders
- Coordination, review and edit of cGMP batch records, specifications, validations reports, CMC regulatory documents (e.g. IMPD, CTA etc.) and other Quality documents
- Coordination of activities for clinical trial supplies

Preferred background

Educational background

- M.Sc. in Pharmaceutical Science, Natural Sciences, Biochemistry, Engineering, or related scientific discipline

Professional experience

- Minimum 5 years of experience from the pharmaceutical or biotech industry in production, QA, QC, supply chain, regulatory and/or development
- Knowledge of cGMP and regulatory requirements for development and production of

pharmaceutical products for phase I/II/III and potential commercial phase
- Experience in working with international cGMP CDMOs for the manufacture and QC of API and Drug Products
- Experience with required content and review of cGMP batch records, stability records, validations reports, and other quality documents
- Specific knowledge within the areas of downstream process elements and/or analytical development and validation will be an advantage
- Handling experience of regulatory documentation related to clinical trial applications would be beneficial but not a requirement

Personal skills

- Good collaboration skills
- Project management skills
- Pro-active, result oriented, flexible
- Cultural awareness
- Holistic mindset
- Ability to work in virtual as well as direct interaction environments
- Fluent in English (spoken & written)

The CMC Specialist will report to our SVP, CMC Development & Project Management.

The position is preferably based in Copenhagen, Denmark but flexibility can be negotiated.

Some travel activities will be required.

Application and further information

If you have any questions to the position, please contact SVP, Bo Persson, phone: +45 31211613 or email: b.persson@varmx.com

Please send your application and CV to SVP, Bo Persson: b.persson@varmx.com

before December 15th.

VarmX *(www.varmx.com) is a young Leiden based biotech company that is focusing on the development of therapies in the field of hemostasis and thrombosis. Originally a spin-off from the Leiden University Medical Center (LUMC), our mission is to develop and manufacture therapeutic proteins to restore hemostasis. Our lead compound, VMX-C001, is intended to safely and effectively restore hemostasis in case of bleeding or emergency surgery in patients taking so-called oral factor Xa inhibitors. The VarmX program has gained significant interest in the investment community and a very successful Series B financing round of €32 mill. was closed in 2020.*