CMC specialist

DESCRIPTION OF MINERVAX
MinervaX is a Danish Company engaged in clinical development (now in phase II) of a Group B Streptococcal vaccine targeting pregnant women for the prevention of life-threatening infections in newborns. So far, the vaccine has been dosed to 300 healthy adult women, and above 50 pregnant women. The vaccine has proven safe, highly immunogenic and giving rise to functionally active antibodies (read more at www.minervax.com). In addition to several ongoing Phase I and Phase II clinical trials, MinervaX is engaged in the development of correlates of protection, which can be used as surrogate markers of efficacy in future Phase III trials.

Minervax offers you an exciting and challenging position in a rapidly growing international oriented company. You will work with highly skilled and experienced colleagues forming a great and successful team.

JOB DESCRIPTION
We are looking for a dynamic and experienced chemistry manufacturing and controls (CMC) specialist to join our team. You have an overall understanding of the CMC area, experiences in working with contract manufacturing and are specialised in one of the following areas:

- Drug substance specialist
  You are experienced in development of microbial upstream and or downstream processes for proteins and GMP manufacturing. As a downstream specialist there is the possibility to assist in building MinervaX internal downstream capacity to support research and development, therefore hand on experience is an advantage.

- Drug Product Specialist
  You are experienced in biopharmaceutical Drug product development and GMP manufacturing in collaboration with contract manufactures, preferably you have experience with aluminium adjuvants

- Analytical specialist
  You are experienced in analytical development and ICH validation of analytical methods in collaboration with contract manufactures and contract laboratories, preferably you are also experienced with ICH stability of biopharmaceuticals

We are looking for someone who is experienced in moving CMC through the development process from early to late stage, with commercial stage in mind. Prior exposure to the global regulatory authorities and working with external CMOs across multiple geographies will be key to success in the role.

In addition to the specialist role, you will be part of the daily operation of CMC, where operational activities such as shipping, writing of internal reports, archiving and a lot of other various activities must be completed.

At a personal level, you must be comfortable operating effectively in a small, dynamic, collaborative, and innovative environment, being able to juggle both strategic tasks and being able to “roll up the sleeves” and to get into the detail, as required. You must possess the energy, passion, and ambition to make a difference in an exciting biotech organization.

This is a unique opportunity to be a contributor to the success of a well-regarded, well financed and well positioned late-stage biotech company.

The specialist will be part of a small CMC team consisting of internal and external CMC experts and will play an important role in driving the CMC development and operations towards phase III and commercial stage.

Job Responsibilities

- Responsible for a specialist area (Drug Substance, Drug Product or Analytical) in collaboration with the Head of CMC
- Collaborations with and oversight of CMO's and CRO's
- Writing of regulatory documents
- Writing of internal reports
- Contribute to general CMC development and operation

Educational background and experience:

- Significant experience in your specialist area and virtual GMP operations
- Experience with outsourcing of downstream processes
- Significant (6+years) experience with drug development and regulatory guidelines, including experience of both early and late phase clinical development, ideally gained in a combination of large pharma and smaller biotech
- Specific experience in vaccine development would be advantageous, as well as additional experience with infectious diseases for example
- The ability to combine strategic thinking with tactical implementation skills, to share the excitement and enthusiasm of the team, and to be comfortable operating in a fast-paced, agile, changing environment

Place of Work

MinervaX is located in Copenhagen, Denmark which is the preferred location to be able to interact closely and on a daily basis with others in the company. Ideally, candidates who are not local should thus be able to relocate for this position. That being said, a reasonable commute allowing the candidate to be in Copenhagen for regular / weekly blocks of time could also work.

Languages

Proficient in English on a professional level, both written and spoken.

General information

For further details or information about the job, please contact CTO, Head of CMC Bjørn Kantsø at bjk@minervax.com or at +45 40 58 11 88