Recruitment of a Sr. Process Specialist, DP for MinervaX Aps

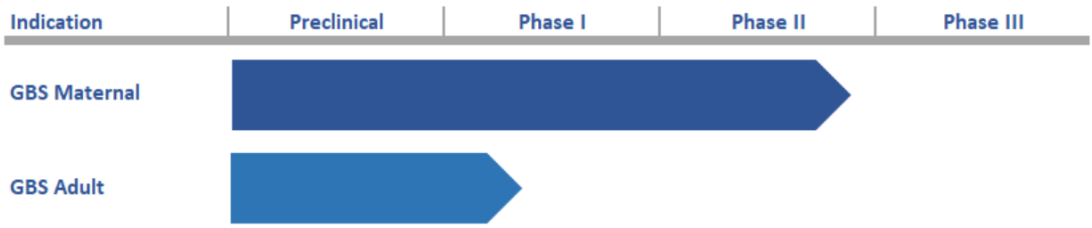
This assignment will be managed by Peter Christensen, PSC SEARCH, please see contact details below.

For further information about MinervaX, please visit the company website at www.minervaX.com.

1. MinervaX Aps

MinervaX is a Danish biotechnology company, established in 2010 to develop a prophylactic vaccine against Group B Streptococcus (GBS) for maternal immunization and the results available until now are very promising. See also www.minervax.com (video)

MinervaX current pipeline:



2. CMC Department, MinervaX

The Company's CMC Department is currently headed by CTO Bjørn Kantsø supported by VP Product Supply and Strategic CMC, Julie Bomholt and Senior Director CTS Nina Svennum as well as several national and international consultants are supporting the department. The supply team is headed by Julie Bomholt and consists of a drug substance specialist, an analytical specialist and the vacant drug product specialist position.

3. The Vacant position: Sr. Process Specialist DP

The position is new and reports to VP Product Supply and Strategic CMC, Julie Bomholt. The position is based at MinervaX new head office, at Nordre Fasanvej 115, Frederiksberg (the former Novo Nordisk site).

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MinervaX is looking for an experienced and dynamic drug product process specialist who brings experience from a similar position. The role will be centered around technology transfer, process upscaling, manufacturing for clinical supply and process validation for commercial manufacturing.

The successful applicant will have a proven record of working within the aseptic processing field and with a track record of hands-on aseptic processing and documentation.

Job Functions in details:

- Lead manufacturing development initiatives, ensuring adherence to GMP standards
- Drive process design and development activities for drug product processes
- Oversee Technology Transfer and upscaling of processes to ensure seamless transitions
- Act as SME in collaboration with external specialists in securing and documenting tech transfer processes and validation activities
- Act as pendant to the external CMO project DP specialists and process engineers
- Supporting manufacturing activities at the CMOs, including follow up on deviation, changes, production metrics, CPV activities and optimization projects
- Act as person in plant if needed
- Reviewing protocols, reports, batch documentation and other related external documentation
- Author internal manufacturing related documentation
- Establish and review specifications for drug product manufacturing
- Write and review Standard Operating Procedures (SOPs) to maintain process integrity
- Contribute to supply planning of drug product
- Collaborate with and oversee activities of Contract Manufacturing Organizations (CMOs) and Contract Research Organizations (CROs) ie review of documentation
- Provide input for regulatory documents and support regulatory interactions
- Contribute to the overall development of the CMC department

4. The Ideal Candidate

4a. Education, Experience and professional competencies

The preferred candidate has ….

- A MSc or PhD in related field e.g. process engineering or biotechnology
- A minimum of 5 years of experience within the field of drug product manufacturing from the pharmaceutical industry
- Extensive experience within aseptic processing and solid experience from a GMP-regulated production environment
- Technology transfer experience / Support technology transfer activities from development to manufacturing
- Experience in establishing and reporting of manufacturing metrics early stage and late stage
- Process validation experience for commercial process validation
- Experience with authoring of validation documentation, including reports, deviations, and change controls.
- Excellent communication and collaboration skills, with the ability to work effectively in a cross functional team environment
- An analytical mindset and ability to troubleshoot complex issues
- Fluent written and spoken English capabilities

Additional preferred qualifications…

- Experience within regulatory and QA requirements (EMEA and FDA regulations) for drug product to be manufactured for market supply
- Experience with leading/participation in risk assessments and provide recommendations for mitigating risks associated with manufacturing processes

4b. Personal skills & competencies

The preferred candidate…

- thrives in a changing and dynamic environment
- has ability to manage details and at the same time ensure a holistic approach towards all steps in the DP manufacturing process
- take responsibility and have the ability to think independently and critically, offering innovative perspectives on tasks and challenges

- has a structured and dedicated mind-set in approaching work and has demonstrated responsibility and accountability to undertake completion of projects in a successful manner
- is flexible and enjoy handling multiple tasks at the same time
- works efficiently and likes to "get things done" in a timely manner
- have a good sense of humour and the interpersonal skills to become a positive, enthusiastic part of the team

Additional Points

Minervax offers you a key role in the CMC department in a rapidly growing and successful international oriented company. You will work with highly skilled and experienced CMC colleagues and play a significant role in the exciting journey for MinervaX towards registration and commercialization of the novel GBS vaccine that will benefit thousands of pregnant women and babies.

This assignment will be managed by Peter Christensen, PSC SEARCH, please see contact details below:

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