Manager/Senior Specialist, CMC Quality Assurance

Minervax offers you an extremely important and challenging position in a rapidly growing and successful international oriented company. You will work with highly skilled and experienced CMC and QA colleagues.

The position is new and reports directly to the VP of Quality, Dorthe Kroun. The position is based at MinervaX new head office at Nordre Fasanvej 115, Frederiksberg (the former Novo Nordisk site).

Job description
The candidate will be responsible for delivering experienced quality assurance support and advice for MinervaX outsourced manufacturing processes and drug product for clinical trials. In daily work He/She will work closely together with the CMC Team on manufacturing quality matters and challenge and approve documents in connection with development, manufacture, stability, and review/dispositioning of clinical batches.
The main purpose in MinervaX QA is to safeguard patient safety and ensure product quality and compliance in the CMC area, and ultimately provide safe drug products for clinical trials and (later) for commercial use.

Main job functions in details

- Ensuring MinervaX products used in clinical trials are following the information and documentation provided to Health Authorities.
- Identifying potential quality gaps and contributing to strengthening CMO production facilities' compliance level and relationship management within.
- Support the continuous improvement of the Quality System including CMC Vendor Qualification, Vendor Lifecycle Management as e.g. Audits (including internal audits) and other QA oversight actions
- Lead Auditor to conduct qualification and recurrent CMO audits
- Responsible for QA oversight of CMC outsourced activities
- QA oversight of CMC out-sourced activities and participation in method transfer and tech transfer activities.
- Be an ambassador in improving the Company quality culture, and promote quality awareness through training, mentoring, and participation in teams and task forces.

Job Requirements

- MSc in Pharmacy, (Bio)Chemistry or similar
- A minimum of 8-10 years in a QA-related role
- Significant experience in Quality Management and Quality Management Systems
- CMC QA experience within method transfer and technology transfer activities.
- Audit experience (conduct or delegate) is mandatory
- Experience with FDA and EMA QA regulations and regulatory authority inspections
- Preferably experience in implementing QMS and Electronic Document Management Systems as such
- Strong communication skills, both in writing and verbally
- Fluent written and spoken English

Personal Attributes
You are a confident self-starter, that possess the capacity for independent and critical thinking. You are comfortable working in a dynamic and fast paced environment being able to handle both long term strategic tasks and more detail-oriented, daily responsibilities.

You will engage with many internal and external stakeholders and need to have high collaborative and communications skills. You have an analytical, structured and regulatory mindset, but yet flexible and able to handling many tasks at the same time. And you have a good sense of humor!

MinervaX is a Danish biotechnology company, established in 2010 to develop a prophylactic vaccine against Group B Streptococcus (GBS), based on research from Lund University. MinervaX is developing a GBS vaccine for maternal immunization, likely to have superior characteristics compared with other GBS vaccine candidates in development. The latter are based on traditional capsular polysaccharide (CPS) conjugate technology. By contrast, MinervaX's vaccine is a protein-only vaccine based on fusions of highly immunogenic and protective protein domains from selected surface proteins of GBS (the Alpha-like protein family). Given the broad distribution of proteins contained in the vaccine on GBS strains globally, it is expected that MinervaX's vaccine will confer protection against virtually 100% of all GBS isolates.

Consultant Peter Christensen, PSC Search, is assisting MinervaX with this recruitment. For further details about the job and the Company, please contact Peter Christensen directly by phone or mail, please see contact details below:

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