Recruitment of a QA Documentation Specialist to the Quality Assurance Team at MinervaX Aps

MinervaX offers you an important and challenging position in a rapidly growing and successful international oriented company. You will work with highly skilled and experienced 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 215, Frederiksberg.

Job description

The QA Documentation Specialist is responsible for managing, organizing, and maintaining all documentation related to the Quality Assurance (QA) processes and procedures. This role ensures that all QA documentation is accurate, up-to-date, and compliant with industry standards and regulatory requirements. The specialist will collaborate with cross-functional GxP teams to ensure documentation supports the overall quality management system.

The candidate will be responsible for delivering experienced quality assurance support and advice for the MinervaX organisation and the quality system within documentation handling, training, archiving and writing/update of new and existing procedures.

The main purpose in MinervaX QA is to safeguard patient safety and ensure product quality, data integrity, compliance and effectiveness of the quality system across the functions, and ultimately provide safe drug products for clinical trials and (later) for commercial use.

Main job functions in details

You will handle various tasks within documentation related to MinervaX quality system, such as:
•Expertise within writing, coordinating, and structuring update of and training in procedural documents.
•Keeping updated on regulatory requirements
•Driving optimization of QA work processes
•Identifying potential quality gaps and contributing to strengthening and continuously improving the existing quality system
•Responsible for QA documentation oversight and archiving

MinervaX ApS
Nordre Fasanvej 215
DK-2000 Frederiksberg
Denmark
www.minervax.com

VAT no. DK32673287

•Be an ambassador in improving the company quality culture, and promote quality awareness through training, mentoring, and participation in teams and task forces.

The Ideal Candidate

•MSc in Pharmacy, (Bio)Chemistry or similar
•A minimum of 3-8 years in a QA-related role
•Collaborative nature and effective communication skills
•Experience in QA/Audits and attention to detail
•Familiarity with FDA and EMA QA regulations and regulatory authority inspections
•Preferably experience in implementing QMS and Electronic Document Management Systems
•Strong communication skills, both in writing and verbally
•Proficient in written and oral English since this is company language.

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 different tasks at the same time both long term strategic and more detail oriented, daily responsibilities.
You will engage with many internal and external stakeholders and need to have good collaborative and communications skills. You have an analytical, structured and regulatory mindset, yet with a flexible and pragmatic interest in reaching the best solution supported by good sense of humour!

MinervaX

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.

For further details about the job and MinervaX, please reach out to
Dorthe C. Kroun, VP QA directly by;
Phone +45 29 49 50 60 or
Mail: dck@minervax.com