Lab Quality Coordinator, GCLP Laboratory, Lund

DESCRIPTION OF MINERVAX

Company

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. Minervax offers you an exciting and challenging position in a rapidly growing international oriented company.

JOB DESCRIPTION

Title

Documentation Coordinator

Your new role

As Lab Quality Coordinator at the laboratory in Lund at MinervaX, you will play a central role in the establishment of a GCLP laboratory for clinical samples from MinervaX's prophylactic vaccine targeting Group B Streptococcus (GBS). The GLCP laboratory is established to move into phase III clinical trials. You will be responsible for the writing, coordination, storage, and maintenance of documentation in the whole laboratory area.

You will be responsible for

- Writing, reviewing, and updating the SOPs relating to GCLP laboratory, general laboratory processes, sample management, and storage.
- Coordinating and planning updates of laboratory quality documents in close collaboration with laboratory employees
- Creating documentation that meets the regulatory requirements within the GCLP area in close collaboration with the Director of Clinical Bioanalysis and QA.
- Dealing with long-term storage of information and data protection (primarily electronic storage)
- Revising outdated documents and assuring they are compliant with laboratory processes.
- Be involved in clinical sample management in the lab.
- Working closely with colleagues in the laboratory to supporting everyone is completing and submitting the necessary documentation.

You will have

- At least 3 years of experience in the pharmaceutical and/or biotechnology industry, either in ISO, GLP, GCLP, or GMP controlled area, responsible/coordinating laboratory documentation, or you have been working within the laboratory and are now looking for a more administrative role outside lab.
- Expertise in writing, coordinating, and structuring laboratory systems and documents and keeping it updated and compliant.
- Structured and organized quality mindset and a high attention to details that you naturally are using in your daily work.
- High collaborative skills, since you will engage with many people in lab
- The ability to react fast on changes and take responsibility of your tasks with a high motivation and dedication.
- Education as minimum bachelor within biotechnology, laboratory technician or similar.

What you'll get in return

This is a unique opportunity to join the journey into building a GLCP compliant laboratory. As this is a new position you can develop this role according to your own ambitions and will be primary person on documentation support. You are offered the opportunity to play an important role in an ambitious and agile company with a small, dedicated team of highly skilled colleagues.

Place of Work

The workplace is Lund in Skåne and if you live in Denmark you will need to commute minimum 3-4 days per week. Working from home will be an option for some days.

Languages

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

GENERAL INFORMATION

For more details about the job, please contact please contact Anna Laurén, Director Clinical Bioanalysis (+46 733 89 31 27) or Tina Biehl, VP Bioanalysis & Analytical Quality (+45 30770303) Please submit your application for recruitment@minervax.com. All applications must be in English and are treated confidentially.