Laboratory IT System owner, GCLP Laboratory, Lund

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
Laboratory IT System owner

Your new role
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). You will be responsible for the software and IT used in the laboratory assuring systems are compliant with regulators requirements.

You will be responsible for
- Full lifecycle system owner for computerized systems including ELN, LIMS, sample management systems, monitoring systems, laboratory equipment software, and similar.
- Creating and updating documentation that meets the regulatory requirements within the GCLP area in close collaboration with the Director of Clinical Bioassays (e.g. CFR 21, part 11 compliance).
- Collaborating with external partners and colleagues in the validating process of the laboratory software and systems (outsourced task).
- Work closely with colleagues in the laboratory to establish good laboratory processes related to software and IT processes.
- Responsible for general software updates and maintenance in the laboratory systems.
- Ensure long-term storage of source data and data protection in laboratory systems.
- Training of colleagues in the laboratory area in data integrity and the ALCOA+ principles.
- Knowledge within CSV and GAMP is an advantage.

You will have
- At least 3 years of experience in the pharmaceutical and/or biotechnology industry, either in ISO or GxP controlled area as IT system owner or similar role.
- High attention to details and a capability to understand the full data flow
- The capability to take full responsibility of IT and Software in the laboratory.
- High collaborative skills since you will engage with many people in the laboratory.
- Education within IT or within pharmaceutical/biotechnology supported by IT postgraduate courses.

What you'll get in return
This is a unique opportunity to join the journey into building a GLCP compliant laboratory. You will work in an ambitious and agile company with a vision to work paperless in a GxP regulated environment in a small, dedicated team of highly skilled colleagues. You will react fast on changes and take responsibility of your tasks with a high motivation and dedication.

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 Rasmus.Bogo@knowit.dk/+45 2948 3820. All applications must be in English and are treated confidentially.