Analytical Quality Director
Job description

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DESCRIPTION OF MINERVAX

Company
MinervaX is a Danish Company engaged in clinical development (now in phase II) of a Group B Streptococcal vaccine targeting pregnant women for the prevention of life-threatening infections in newborns. So far, the vaccine has been dosed to 300 healthy adult women, and so far 53 pregnant women. The vaccine has proven safe, highly immunogenic and giving rise to functionally active antibodies (read more at www.minervax.com). MinervaX is currently engaged in several Phase I and Phase II clinical trials, and epidemiological studies to develop serocorrelates of protection, which can be used as surrogate markers of efficacy in future Phase III trials.

Minervax offers you an exiting and challenging position in a rapidly growing international oriented company. You will work with highly skilled and experienced colleagues forming a great and successful team.

JOB DESCRIPTION

Title
Clinical Project Manager

Your new role
MinervaX is a growing company now entering into phase II clinical trials. MinervaX is establishing a development laboratory staffed by scientist and technicians who will be developing, qualifying and executing analytical methods for analysis of vaccine responses in samples from clinical trials and help develop biological analytical assay for manufacturing quality control. The lab will not initially be running a GLP environment but will implement the basic principles.

You will be responsible for
- Implementation of basic quality systems throughout the lab
- Implementation of documentation and reporting procedures
- Training personnel in lab and affiliated research groups in quality and reporting procedures
- Writing analytical qualification protocols, analytical reports and certificates of analysis
- Participating in development, qualification and execution of analytical assays, when appropriate
- Assay transfer to GLP certified CROs
- Regulatory Support

You will have
- At least 5 years of experience from the pharmaceutical industry or analytical CRO
- Experience with development of analytical assays, preferably ELISA and/or bacterial assays
- Experience with qualification/validation of analytical assays
- Experience with quality and reporting systems required for pharmaceutical development
- Experience with GLP, and preferably educated GLP Study Director

• Structured and organized quality mindset
• The ability to remain calm under pressure
• The ability to problem solve without supervision or guidance
• A high level of professionalism
• The ability to maintain confidentiality and to use discretion in all interactions

What you'll get in return

This is a unique opportunity for you to develop the lab into a lab working towards GLP-similar standards. As this is a new position you can shape and develop this role according to your own ambitions. No standards exist and you are the one who decides how to apply the standards and requirements. You are offered the opportunity to play a key role in an ambitious and agile company with a small, dedicated team of highly skilled colleagues.

Reference

You will report to the Senior Director of Regulatory and Quality in the parent company in Denmark.

Place of Work

The work place is Lund in Skåne, but if you live in Denmark, it is possible to work in a combination from Lund and the office in Copenhagen.

Languages

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

GENERAL INFORMATION

For more details about the job, please contact Headhunter Tine Nielsen, at Hays on tine.nielsen@hays.dk

link_to_job