Medical Director/VP Clinical Operations
Job description

12 April 2021
Per Fischer

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). In addition to several ongoing Phase I and Phase II clinical trials, MinervaX is engaged in the development of correlates of protection, which can be used as surrogate markers of efficacy in future Phase III trials. The correlates of protection are based on measuring natural immunity to GBS in pregnant women and correlating it to risk of invasive neonatal GBS disease, in order to develop predicted thresholds of protection. MinervaX is engaged in several CoP studies around the world, either through academic collaboration or via a local CRO.

Minervax offers you an exciting 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
Medical Director/VP Clinical Operation

About the position
We are looking for a dynamic, experienced Medical Director/VP Clinical Operations to join our team. The candidate will be reporting to the Chief Medical Officer

We are looking for someone who has moved assets through the development process, specifically with experience in late phase development. Prior exposure to the global regulatory authorities and working with external CROs and relevant clinicians across multiple geographies will be key to success in the role.

At a personal level, you must be comfortable operating effectively in a small, dynamic, collaborative, and innovative environment, being able to juggle both strategic tasks and being able to “roll up the sleeves” and to get into the detail, as required. You must possess the energy, passion, and ambition to make a difference in an exciting biotech organization.

This is a unique opportunity to be a contributor to the success of a well-regarded, well financed and well positioned late-stage biotech company.

The Medical Director will help build and head a small team (e.g., Clinical Project Managers and Clinical Research Associates), and will play an important role driving progress and providing leadership to the Clinical team.

Job Responsibilities

- Together with the CMO, define and develop the strategy for the implementation of clinical programs, including collaboration with clinicians, investigators, KOLs and partners; ensuring that the clinical strategy meets the overall business objectives and with timely and accurate insight into market and therapeutic area development.
- Ensure the delivery of clinical translation in line with the scientific and commercial aims of the pipeline, as effectively and efficiently as possible.
- Manage external clinical CROs, pharmacovigilance, regulatory interactions, etc.
- Support / engage as required with non-clinical development activities to support the company's strategic and commercial goals.
- Together with the CMO, ensure compliance with all clinical, legal, and regulatory requirement and be accountable for all aspects of patient safety relating to your operations and trials; provide emergency safety advice cover during ongoing trials.
- Ensure appropriate and continuous medical risk/benefit assessment during the development of your portfolio and that quality systems are fit for purpose.

Educational background and experience:

- Medically qualified or other relevant university degree (e.g., Pharmacy or Clinical Sciences)
- Significant (8+years) experience with drug development and regulatory guidelines, including experience of both early and late phase clinical development, ideally gained in a combination of large pharma and smaller biotech
- Specific experience in vaccine development would be advantageous, as well as additional experience with infectious diseases for example
- A results/solutions orientation and attention to detail, supported by strong project and planning management skills
- The ability to combine strategic thinking with tactical implementation skills, to share the excitement and enthusiasm of the team, and to be comfortable operating in a fast-paced, agile, changing environment
- A self-starter with an eye on results, who is driven to deliver quality results on time and in a highly ethical and professional manner

Place of Work

MinervaX is located in Copenhagen, Denmark which is the preferred location to be able to interact closely and on a daily basis with others in the company. Ideally, candidates who are not local should thus be able to relocate for this position. That being said, a reasonable commute allowing the candidate to be in Copenhagen for regular / weekly blocks of time could also work.

Languages

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

GENERAL INFORMATION

If you would like to apply, please send an application and a CV to c.visholm@coulterpartners.com.
For more information, you can also send an email to the same address.