PSC SEARCH

Sr. Clinical Trial Manager

Vicore Pharma AB

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Recruitment of a Senior Clinical Trail Manager (Sr. CTM) for Vicore Pharma AB, based in Denmark.

This document is intended to provide a brief overview of Vicore Pharma covering such aspects as its history, business strategy, pipeline and future plans, together with an outline specification for the open position as Senior Clinical Trial Manager.

For further information about Vicore Pharma, please visit the company website at www.vicorepharma.com.

1. Vicore Pharma AB

Vicore Pharma is a clinical-stage pharmaceutical company focused on developing innovative medicines in severe lung diseases where the Angiotensin II type 2 receptor (AT2R) plays an important role. Embedded in the Company's search- and development approach is the determination to find solutions for conditions which have an enormous deleterious impact on patients and their families and to transform the lives of those affected.

Vicore Pharma was founded in 2000, following research at Uppsala University and the Sahlgrenska Academy, and originally funded by venture capital. In December 2015, the Company completed an equity issue and was publicly listed on Nasdaq First North.

In the summer of 2018, with new Venture Capitalist backing from HealthCap, Vicore Pharma further strengthened its financial position. With the new funding, these transformational medicines can be effectively moved closer to patients. In September 2019 Vicore Pharma listed its shares on Nasdaq Stockholm (Small Cap).

Vicore Pharma has offices in Stockholm, Gothenburg and in Hørsholm, Copenhagen.

2. The Vacant position: Sr. Clinical Trial Manager

Vicore Pharma is constantly expanding the development pipeline and aims to strengthen the organization by hiring a new Senior Clinical Trial Manager to join the team. He/She will contribute across the product lifecycle of Vicore's therapies and one of the main focuses will be handling of the next trial in IPF, currently under planning.

The position reports to Sr. Director, Anne Katrine Cohrt and will work closely with the Clinical Operations and Regulatory Teams and also with external consultants and CRO vendors.

The position is a full-time position and will be based at Vicore Pharma's offices in Hørsholm, Denmark. About 10-20 travel days per year to both the company's HQ in Stockholm and to CRO's can be expected.

Role summary and responsibilities

- Act as lead and coordinator for the clinical trial team and be overall responsible for trial related timelines and activities from start up to final clinical trial report in close collaboration with internal clinical team members and vendors
- Securing trial deliverables in a proactive and motivational fashion, through transparent communication and teamwork throughout all stages of trial conduct
- Assure the quality of every aspect of the trial by incorporating GCP compliance and by following appropriate standard operating procedures (SOPs), instructions and other written agreements and other clinical trial/ protocol specific guidelines/ documents as applicable
- Participate in risk assessment/management
- Escalations of issue(s) as appropriate
- Development and monitoring of trial budgets
- Development and monitoring of project timelines
- Participate in the clinical trial outsourcing process for relevant trials, by being involved in identifying and selecting vendors, and managing vendor performance
- Ensuring sponsor engagement and sponsor oversight activities by overseeing vendor deliverables and escalating issues, as required
- Create, review and/or approve (as applicable) trial documentation with the in-house team and selected vendors
- Ensure proper documentation and filing to allow for accurate reporting, interpretation, and verification of trial information together with the clinical trial team
- Responsible for an up-to-date clinical Trial Master File throughout the clinical trial together with the CTA.

3. THE IDEAL CANDIDATE

3a. Education, Experience and professional competencies

The ideal candidate will have a relevant life science background. He/she will bring several years' experience from a similar Clinical Trial Manager role; preferably in a small or medium size pharma/biotech company.

The candidate must have an entrepreneurial mind-set and be a trustworthy communicator able to communicate scientific information on a high but understandable level.

In summary

- Master's or Bachelor's degree in relevant educational areas, e.g. MSc. in Pharmacy, Nurse or similar.
- Solid experience (a minimum of 5 years) of managing multicenter, international clinical trials (phase 1 to 3, where experience with phase 2b/3 is a must). Biotech experience is a preference.
- Extensive knowledge of all aspects of the clinical trial process and documented experience in ICH GCP including risk management and sponsor oversight
- Demonstrated ability to lead multi-disciplinary teams
- Experience from leading clinical trials through global clinical outsourcing

- Experience with decentralized virtual trials set up is an advantage as well as experience with US study regulations is an advantage
- Experience with protocol development
- Interest in data evaluation and interpretation can be an advantage
- Proficient in English both verbal and in writing

3b. Personal skills & competencies

The preferred candidate will have a strong drive and like the idea of working in a small company setting.

The candidate must be a team player with a strong we-mentality but also be able to work independently with a minimum of directions. He/she will bring to the role a proactive, structured and efficient style of working, be able to take new initiatives and if needed think out of the box.

In summary

- Strong interpersonal skills, ability to communicate and manage well at all levels and with both internal colleagues/CMOs/external consultants etc.
- Leadership and coaching skills
- Entrepreneurial mind-set, understanding and appreciating the challenges and opportunities of working in a small company setting
- Structured, organized and detail oriented but able to maintain helicopter-view
- High energy and passion for getting things done
- Proactivity and ability to work with minimal supervision
- Ability to challenge the status quo and identify better ways to work and achieve goals
- Able to make judgements and decisions incorporating both scientific integrity and business understanding
- Team player with a “we” mentality

4. SELLING POINTS

The position as Sr. Clinical Trial Manager at Vicore Pharma is a unique chance for an ambitious candidate with substantial experience within planning and execution of clinical trials to take a leading role in Vicore’s Clinical Operations team.

The Company has a very interesting development pipeline and a promising business strategy and you will become part of an exciting journey with an extremely pleasant and professional team in a flexible working environment.

5. TERMS & CONDITIONS OF EMPLOYMENT

The salary and terms of employment will be discussed in detail at the final company interview. The following should serve as a guide only.

- Attractive, experience-related salary
- Pension, 12.5%
- Participation in the Company's bonus and stock options program
- Other fringe benefits incl. lunch arrangement

6. Communication and Contact

This assignment will be managed by Peter Christensen, PSC SEARCH, please see contact details below:

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