PSC SEARCH

Senior Manager/Assoc Director CMC

Vicore Pharma AB

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Business Address: Strandvejen 100, 2900 Hellerup

PSC SEARCH

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Recruitment of a Senior Manager/Assoc. Director CMC for Vicore Pharma AB, preferably 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 Manager/Assoc. Director CMC.

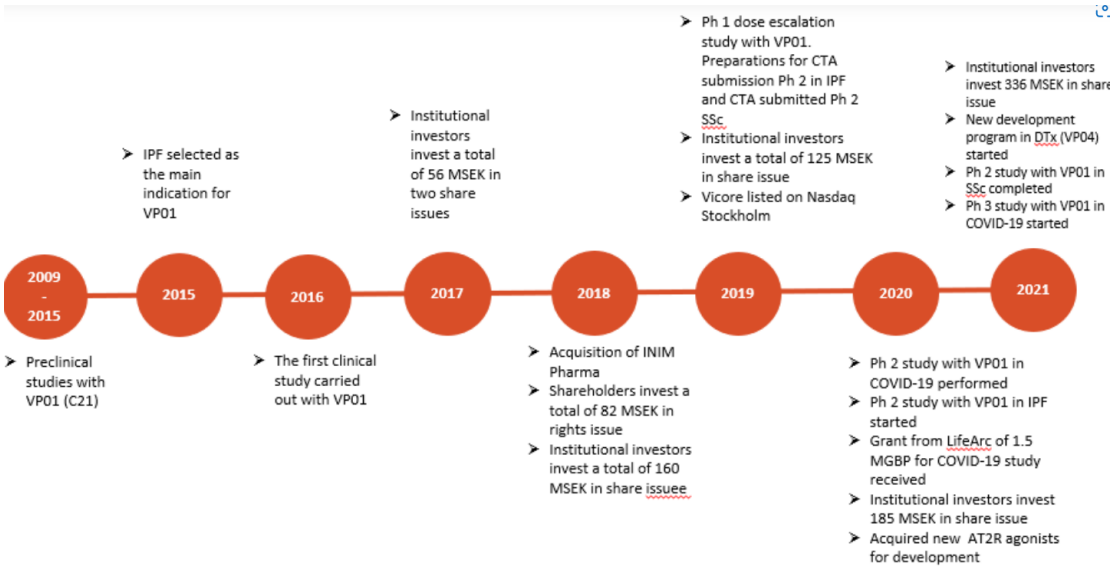
For further information about Vicore Pharma, please visit the company website at www.vicorepharma.com.

1. Vicore Pharma AB

Vicore Pharma is a clinical-stage pharmaceutical company founded in 2000 focused on developing innovative medicines in severe 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.

The company's shares (VICO) are listed on Nasdaq Stockholm main market. Vicore Pharma has offices in Stockholm, Gothenburg and in Hørsholm, Copenhagen.

History:



Pipeline and Clinical Development Pipeline

The company currently has four development programs: VP01, VP02, VP03 and VP04.

VP01 aims to develop the substance C21 for the treatment of idiopathic pulmonary fibrosis (IPF), COVID-19 and pulmonary arterial hypertension (PAH).

VP02 is a new formulation and delivery route of thalidomide and focuses on the underlying disease and the severe cough associated with IPF.

VP03 includes the development of new AT2 receptor agonists (ATRAGs) for numerous indications.

VP04 develops a clinically validated digital therapeutic for IPF patients.

Please see the pipeline overview in the figure below:

Indication	Compound	Preclinical	Phase 1	Phase 2	Phase 3	Next event
COVID-19	C21					Phase 3 read-out H2 2022
IPF fibrosis	C21					Phase 2 read-out H2 2022
PAH	C21					Phase 2 start Q4 2022 / Q1 202
IPF anxiety	DTx					Clinical trial 2022
IPF cough	Inhaled IMID					Formulation development
Multiple indications	C106					Phase 1 2022

For further information, please see Vicore Pharma's webpage: www.vicorepharma.com.

2. ORGANIZATION

Vicore Pharma Management

Vicore Pharma is headed by CEO Carl-Johan Dalsgaard together with a senior and professional management team of highly skilled people located in Stockholm, Gothenburg, Copenhagen and London. Please see details and more information about the Management group at www.vicorepharma.com.

Pharmaceutical Development, Vicore Pharma

Pharmaceutical Development is headed by Director, Stine Furbo. Stine holds a Candidate degree in Applied Chemical Engineering from DTU, an EBA and MMPI from CBS SIMI and has many years of experience within drug development and CMC project management. See also: linkedin.com/in/stinefurbo.

3. The Vacant position: Sr. Manager/Assoc Director CMC

Vicore Pharma is expanding the development pipeline and aims to strengthen the organization by hiring a Senior Manager/Associate Director CMC to join the team. You will get the opportunity to learn and contribute across the product lifecycle of our therapies although the main focus will be in the VP03 program and to be part of the development of new AT2 receptor agonists.

Vicore Pharma development program includes small molecules for oral administration, inhalation- and sterile products.

The position is new and reports to Director, Pharmaceutical Development. You will work closely with especially the Clinical Operations and Regulatory Teams and also with external consultants and CMO vendors.

The position is a full-time position and will, preferably, be based at Vicore Pharma's offices in Hørsholm, Denmark, it is a requirement that the candidate is located in 'commuter distance' to Copenhagen region – either in Sweden or Denmark. About 15-25 travel days per year to both the company's HQ in Stockholm and CMO's can be expected.

Role summary and responsibilities

- Lead the pharmaceutical development of drug substance and drug product from pre-clinical phase and throughout phase 3.
- Plan the CMC development path and timelines in alignment with the overall project strategy e.i. with pre-clinical, clinical, regulatory, and commercial strategies together with the Director, Pharmaceutical Development
- Ensure timely delivery of API and investigational medicinal product (IMP) for pre-clinical and clinical activities and coordinate packaging and supply with the Clinical Trial Manager
- Keep oversight of CDMO's/CMO's and follow up on activities
- Act as scientific expert review and approve all relevant CMC documentation related to the product/project.
- Participate in selection of potential new CMO vendors based on project needs.
- Review and approve regulatory CMC documentation e.g., clinical trial applications, INDs, IMPDs and briefing documents
- Participate in meeting with regulatory agencies and health authorities if required
- Contribute to adequate filing and archiving of CMC documentation
- Contribute to developing SOP processes and writing SOP's

4. THE IDEAL CANDIDATE

4a. Education, Experience and professional competencies

The ideal candidate will have a relevant scientific background. He/she will bring several years' experience from a similar CMC management/CMC project management 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

- PhD or MSc in Pharmacy, Chemistry, or other relevant scientific background
- A minimum of 8-10 years' experience in drug development and/or CMC project management from the pharmaceutical/biotech industry
- Extensive experience in cGMP
- Knowledge and understanding of GLP, GCP and GDP regulations
- Experience in managing outsourcing activities related to development and manufacturing
- Extensive experience in reviewing of CMC regulatory documentation
- Experience with small molecules development is preferable
- Proficient in English both verbal and in writing.
- Strong computer skills with ability to work in a paperless office.

4b. Personal skills & competencies

The preferred candidate will have a strong drive and like the idea of working in a small virtual 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.
- 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
- Pragmatic, flexible, positive, enthusiastic

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

- Participation in the Company's bonus and stock options program
- Other fringe benefits

6. Communication and Contact

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

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