

Job Description – Global Project Leader with responsibility also as Clinical Research Manager (dual role)

We are a passionate growing company focusing on development of new innovative therapies for the treatment of severe disorders that affect the central nervous system, such as Alzheimer's disease and pain.

Are you our new project leader?

Position Title

Global project leader with responsibility also as clinical project leader (dual role)

Department/subsidiary

AlzeCure Pharma is a growing pharmaceutical company, devoted to developing new treatments for patients suffering from neurodegenerative diseases and chronic pain. Please visit our website for further information <https://www.alzecurepharma.com>

In this dual role you will be part of the small but dedicated and highly experienced global development team.

General information

This is a temporary position, duration of approximately 12 months, since the permanent position holder will be on parental leave. Start date is ideally February or March 2022.

The role is based at AlzeCure Pharma's HQ in Huddinge, outside Stockholm, Sweden.

You would be leading a cross-functional global project team consisting of a mix of internal and external experts, and additionally be responsible for the oversight and management of clinical trial activities outsourced to CROs. You are key in leading and driving the projects towards defined goals and according to timelines, quality and budget. The applicable project is currently in clinical phase I.

The position is key in leading and driving our development projects forward.

Here's what you will do: As Global Project Leader

Your key responsibilities will be:

- Lead the project team that is responsible for the global development of a novel drug candidate. This project team includes representation from relevant functions, including clinical development, CMC, regulatory and non-clinical development.
- Lead the work related to the long-term planning of the product development strategy as well as co-ordinate the operational activities for the project in the short-term.
- Manage and oversee the project timelines, resources and overall project budget.
- Drive risk management process on a global project level.
- Report the project progress to the AlzeCure leadership team and Board of directors.

As Clinical Research Manager

Your key responsibilities will be:

- Together with the Medical Program Director, manage activities within the project clinical development plan, including all ongoing clinical trials, publications, submission of annual reports (DSURs), advisory meetings, building KOL network and other initiatives as relevant.
- Lead the operational execution of planned clinical trials according to agreed timelines, budget, ICH-GCP and SOP quality standards and operational procedures.
- Drive the process of identifying external service providers, including clinical CROs, develop request for proposals and manage bidding process. Be the primary contact person throughout the contracting process and throughout the management of the trial.
- Perform ongoing sponsor oversight of all contracted external service providers, including review of study plans and key documents and oversee risk management and risk-based monitoring activities. Ensure documentation of oversight activities accordingly.
- Collaborate with the QA manager to ensure audits and ongoing vendor quality review is performed as required.
- Coordinate the internal contribution for the compilation of critical documents, such as the Study Protocol, amendments, CRFs, Informed Consent forms and Study Reports in collaboration with the selected CRO.
- Responsible for ordering and management of investigational medicinal products (IMPs) and other clinical trial materials.
- Oversee the set-up and maintenance of the Trial Master File managed by the CRO.
- Ensure compliance with clinical registry requirements, such as ClinicalTrials.gov.
- Oversee and follow up on budget and costs for individual clinical trials.

As Global Project Leader/Clinical Research Manager you need to have:

- 5 years or more experience as a Clinical Trial/Project Manager in the pharma/ life science /biotech industry
- Preferably experience in leading global product development projects
- Preferably experience within Neurosciences (pain and/or Alzheimer studies)
- Extensive oversight experience
- Life science degree
- Motivates and ensures team effectiveness through eliciting feedback
- Excellent communication, presentation and problem-solving skills
- Budget and resource forecasting skills
- Experience with managing vendors/external service providers
- In depth knowledge of GCP requirements
- Excellent written and oral communication skills in English

Skills/Knowledge/Languages

- Required: English
- Desired: Swedish

Personal Attributes

Required:

- As a person you should be highly entrepreneurial, with a strong personal drive, organizational skills and a high level of accountability. A “can-do-attitude” focusing on actions not problems.
- Excellent problem-solving abilities.
- Is curious, positive, pro-active and likes working in a fast-growing environment where functions and processes are still in development and enjoys contributing to building up the structures.
- Demonstrate a drive for results.
- Is willing to travel occasionally.
- Is willing to perform also CRA level duties.
- Strong customer-oriented mindset.

If you are the right candidate for this position, please send in your CV and a personal letter to info@alzecurepharma.com by 12 Jan 2022. However, don't wait, submit it in today since we will conduct interviews continuously. Please feel free to contact Märta Segerdahl, Chief Medical Officer +46 (0) 73 680 88 98 with any questions regarding this position.

Company Background

AlzeCure Pharma AB (publ) is a Swedish pharmaceutical company that develops new innovative drug therapies for the treatment of severe disorders that affect the central nervous system, such as Alzheimer's disease and pain - indications for which currently available treatment is very limited. The company is listed on Nasdaq First North Premier Growth Market and is developing several parallel drug candidates based on the three research platforms, NeuroRestore®, Alzstatin® and Painless.

NeuroRestore comprises three symptom-relieving drug candidates where the unique target mechanism opens up for multiple indications – Alzheimer's disease, but also cognitive dysfunction in traumatic brain injury, sleep apnea and Parkinson's disease.

Alzstatin is comprised of two disease modifying and preventive drug candidates for treatment of early Alzheimer's disease.

Painless, which is the company's research platform in the field of pain, contains two projects: VR1/ACD440 which is a clinical candidate for the treatment of neuropathic pain, and TrkA-NAM that is targeting pain disorders such as osteoarthritis.

AlzeCure® aims to pursue its own projects through preclinical research and development to an early clinical phase.

FNCA Sweden AB, +46(0)8-528 00 399, info@fnca.se, is the company's certified adviser. For further information, please visit our website at www.alzecurepharma.se.