AUREALIS PHARMA

Open Position:

Do you have the passion, ambition and dedication to create new life-saving treatments for patients at need?

Aurealis Pharma is a vibrant, open-minded and motivating biotech. We are expanding and have an exciting opportunity for a high caliber individual to join our team as a:

Clinical Program Manager / Head of Clinical Operations

Employer: Aurealis Pharma AG/Aurealis OY

Employment Type: Full Time (permanent)

Location: Hochbergerstrasse 60C, Basel, or Microkatu 1, Kuopio, Finland

Start Date: As soon as possible (dependent on qualified candidate availability)

Position Summary:

You will be responsible for the planning, preparation, execution and management of clinical studies according to required quality standards, on schedule and within budget. You will oversee and manage the activities of CROs and are responsible for preparation of relevant clinical documents (protocols, reports, IB, IMPD, CTA). Your primary task is to manage our lead product AUP-1602C first-in-human phase 1-2A clinical studies in diabetic foot ulcer. You will report to the Chief Medical Officer of the company. Location can be either Switzerland or Finland, depending on the qualified candidate availability.

Responsibilities:

- Development of study protocols and other study related documents by coordinating input from internal team members and external sources.
- Implement trials, including CRO selection, feasibility studies, investigator identification, timeline management, investigator communication, monitoring, and budget maintenance.
- Oversight of clinical trial operations as performed by a CRO or other external consultants.
- Evaluate potential vendors, negotiate budgets, and finalize contracts.
- Preparation and set-up of internal SOPs related to GCP requirements.
- Manage multiple clinical studies according to GCPs, SOPs, protocol and local regulations.
- Develop tools and processes that increase measured efficiencies of the project.
- Tracks items related to CDAs, budget and contract completion status.
- Managing and mentoring junior staff members.

Preferred Education:

- Bachelor/Masters/PhD degree in Life Sciences or health-related field required. Other educational qualification may be accepted in relation to experience in managing clinical programs and studies.

Qualification & Preferred Experience:

- Minimum of 5 years of experience in all operational aspects of managing clinical trials in a leadership role using CROs (protocol development, study implementation, study management, monitoring, and study report preparation).
- Minimum of 2 years of experience managing external vendors and CROs.
- Area(s) of expertise preferred: **Diabetes, Diabetic foot ulcer/chronic wounds**, dermatology, vascular surgery, orthopedics, oncology.

- Area(s) of expertise desired: Clinical, immunology, biology, bioengineering, cell or molecular biology, experience with cell-based therapies is preferred and clearly an upside.
- Global/multi-national experience, preference for EU.
- Early phase 1 and 2 clinical program experience including clinical pharmacology studies.
- Must have a demonstrated working knowledge of GCP, ICH guidelines, and EMA regulations (additional knowledge of FDA regulations will be an upside) and experience with managing all phases of a study, all CRO-related activities, site identification and qualification through final study report generation.
- English as a professional working language. German, Finnish, and/or Swedish is a plus.

Preferred Computer & Special Skills:

- Proficient in Word, Excel, Project and PowerPoint or equivalent required.
- Strong leadership and management skills.
- Excellent teamwork and collaboration skills.
- Effective process and project management skills.
- Outstanding written and verbal communication skills.
- Expert knowledge of scientific principles and concepts.
- Ability to multi-task as needed in a small company environment.
- Able to resolve routine issues independently and provide possible solutions to senior management for complex issues.
- Can effectively cope with change and can make good decisions without having the complete picture.
- Must have demonstrated problem solving abilities in overseeing clinical studies with external CROs.

The position will require **travelling up to a level of 25 %** overall working time.
The above statements are intended to describe the general nature and level of work being performed by people assigned to this classification. They are not to be construed as an exhaustive list of all responsibilities, duties, and skills required of personnel so classified. All personnel may be required to perform duties outside of their normal responsibilities from time to time, as needed and flexibility is required when working for a small start-up, biopharmaceutical company.

Aurealis Pharma AG / Aurealis Oy is a Swiss-Finnish biopharmaceutical company developing a broadly applicable technology platform facilitating protein/antibody combination therapy embedded in one single product that can be administered in a safe, efficient and cost-effective way. Safe food-grade lactic acid bacteria produce and secrete multiple therapeutic human proteins locally in target tissue. Our first products are immuno-therapeutics targeting chronic inflammatory wounds and cancer. Our lead development candidate AUP1602-C is ready to move forward into first-in-human phase 1-2A study and the preparation and set up of this study will be the focus for the engagement with Aurealis Pharma AG.

For consideration, please email a brief cover letter describing your qualifications and a CV to CMO Dirk Weber (dirk.weber@aurealispharma.com) with cc. to CEO Juha Yrjänheikki (juha@aurealispharma.com).
For ease of processing, please put “Aurealis - Clinical Program Manager” in the subject line.

Sincerely,

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