2800 Meridian Parkway, Suite 195
Durham, North Carolina 27713
www.parion.com

AVAILABLE POSITION: VICE PRESIDENT, CLINICAL OPERATIONS

Parion Sciences is a development stage biopharmaceutical company dedicated to research, development, and commercialization of treatments to improve and extend the lives of patients with respiratory diseases. Parion has a diverse pipeline of pre-clinical and clinical candidates for the treatment of these diseases via novel mechanisms of action.

Our lead program, P-1037 Inhalation Solution (P-1037 IS), is preparing to start global Phase 3 development for the treatment of Primary Ciliary Dyskinesia, a rare, serious disease with no approved treatments available. P-1037 IS, an epithelial sodium channel (ENaC) inhibitor, formulated for delivery by inhalation, is the first and only treatment in clinical development for PCD.

Parion is at the forefront of ENaC inhibitor development and is leveraging our scientific expertise in epithelial biology to expand our platforms and advance novel compounds for treatment of muco-obstructive respiratory diseases such as severe asthma, cystic fibrosis, primary ciliary dyskinesia, bronchiectasis, chronic obstructive pulmonary disease and viral infections in the lung.

The Parion team, located in Durham, NC, is comprised of accomplished leaders and talented, passionate colleagues with a desire to help the patients we aim to treat.

Ideal Candidate:

The Vice President of Clinical Operations will be responsible for the leadership, oversight and execution of the company's clinical trials, ensuring they are completed according to timelines, budgets, and regulatory/corporate quality standards. The Vice President will report to the Chief Executive Officer, and will serve as a functional leader, line manager and subject matter expert for clinical operations. The incumbent will work collaboratively with other senior leaders to achieve corporate objectives and initiatives. With extensive industry knowledge and experience, the Vice President will proactively seek to develop strategies necessary for successful enrollment, data collection, assessment, analysis, and reporting to gain regulatory approval of P-1037 IS, as well as to improve the efficiency, effectiveness, and quality of the Company's clinical trial capabilities. The incumbent will ensure all clinical studies are conducted in accordance with company SOPs, GCPs and ICH guidelines.

Job Description/Responsibilities:

- Implement and execute the P-1037 IS global clinical development plan:
    - Develop collaborative alliances and relationships with external service providers, investigators and clinical site staff
    - Identify and manage external contractors and vendors as needed to ensure project objectives are met within required timelines and budget
    - Ensure studies are performed to regulatory standards and all elements are included to meet submission requirements

- Provide Clinical Operations expertise, leadership, and input to project teams, commercial, regulatory, fundraising, due diligence and other projects that may arise from senior management
- Develop clinical operations strategy for successful delivery of clinical studies within timelines and budget
- Supervise outsourcing of clinical studies to CROs/vendors:
    - Manage forecasting, budgets, contract compliance, timelines
    - Ensure scope of contract with CRO and vendors addresses all anticipated issues with study conduct and minimizes the need for change orders.
    - Ensure collected data are complete, reviewed, and issues are appropriately resolved, on an ongoing basis
- Ensure SOPs, manuals or checklists (working document) are implemented in order to facilitate tasks efficiently
- Develop clinical protocols to support the company's product strategy and ensure data collection/management and clinical study reports are developed in compliance with appropriate standard operating procedures, regulatory, medical standards and quality, in accordance with FDA, EMA, GCP, and ICH guidelines.
- Contribute to development/maintenance of SOPS, as subject matter expert, including clinical and vendor management related SOPs
- Prepare/review and/or manage clinical trial agreements, informed consent forms, case report forms, study procedures manuals, clinical study reports and other clinical documents as necessary
- Ensure development, review and execution of activities outlined in various study plans, e.g., data management plan, safety management plan, sample management plan, CRF completion guidelines, eCRFs, IWRS system specifications, and clinical supply/packaging/distribution plans
- Assure compliance of monitors, consultants, investigators, and vendors with study procedures/manuals, GCP, SOPs and guidelines
- Lead meetings for internal clinical team members, CROs, vendors and partners, as needed
- Manage investigator meetings
- Hire, train and supervise employees; foster the growth and development and provide mentorship for the clinical development team
- Oversee performance management and career development for direct reports
- Perform other duties as required and assumes other responsibilities as assigned by the CEO

Minimum Requirements:

- Advanced degree with science/life science concentration or commensurate experience
- Fifteen years of clinical experience, including managing CRO activities for international multi-center Phase 3 trials
- Knowledge of regulations relating to clinical drug development and ICH GCP
- In addition, must possess:
    - Strong organizational and management skills
    - Ability to manage multiple priorities and establish and meet deadlines.
    - Excellent interpersonal skills
    - Ability to ensure details are consistently accurate
    - Ability to mentor and collaborate with others and work effectively
    - Ability to thrive in a fast-paced environment and adapt to rapidly evolving needs

- Proficient with Microsoft Word, PowerPoint, Excel, Teams and web-based systems.
- Ability to travel <10% of time
- Flexible work environment: Hybrid model encompassing both in-person office participation at our Research Triangle site and the ability to work remotely part time

Preferred Skills/Experience:

- Knowledge of respiratory clinical trials
- Knowledge of GDPR requirements and other data privacy requirements
- Experience with international multicenter trials
- Experience with pediatric and/or rare disease clinical trials

Anticipated Start Date: Immediately

Qualified candidates, please e-mail resumes with references to Careers@Parion.com

What We Offer:

- A competitive salary
- Ability to make a meaningful impact as the first treatment to enter Phase 3 in this rare disease
- Exceptional opportunities for learning and growth
- Stock Options
- Company-paid holidays
- Paid time off
- Health and dental insurance
- Disability
- Life insurance401(k) plan + match

Parion Sciences is an equal opportunity employer and is committed to providing equal employment opportunities without regard to age, race, color, religion, sex, national origin, disability, protected veteran status, sexual orientation, gender identity or any other protected class.

To all agencies: Please, no phone calls or emails to any employee of Parion Sciences about this requisition. All resumes submitted by search firms/employment agencies to any employee at Parion Sciences via-email, the internet or in any form and/or method will be deemed the sole property of Parion Sciences, unless such search firms/employment agencies were engaged by Parion Sciences for this requisition and a valid agreement with Parion Sciences is in place. In the event a candidate who was submitted outside of the Parion Sciences agency engagement process is hired, no fee or payment of any kind will be paid**.**