

Parion Sciences is a development stage biotech company dedicated to research, development, and commercialization of treatments to restore patient's innate mucosal surface defenses.

AVAILABLE POSITION: MANAGER, CLINICAL OPERATIONS

Job Description/Responsibilities:

- Manage Contract Research Organizations (CROs) and other external vendors to ensure successful
 clinical trial implementation including monitoring or co-monitoring with CRO as needed
- Liaise with clinical sites as appropriate to ensure optimal Sponsor-site relationships
- Prepare/review clinical study protocols, informed consent forms and other patient tools, study procedures manuals, clinical study reports and other clinical documents as necessary
- Assist in development of CRF including CRF completion guidelines and edit checks
- Manage investigator meetings
- Ensure development, review and execution of activities outlined in various study plans, e.g., data management plan, safety management plan, sample management plan
- Partner with clinical supply planning team to provide drug supply assumptions
- Assure compliance of monitors, consultants, investigators, and vendors with study procedures/manuals, good clinical practice, standard operating procedures and guidelines
- Manage study budgets, project timelines and ensure accurate and timely updates
- Manage initial and subsequent CTAs
- Manage all aspects of study progress from planning to close-out through CROs to assure adherence to intended timelines and achievement of study goals while ensuring quality in accordance with FDA, EMA, GCP, and ICH guidelines.
- Perform other duties as required and assumes other responsibilities as assigned by the supervisor/manager.

Minimum Requirements:

- BS in science/life science degree or commensurate experience
- Five+ years of clinical experience in multi-center trials managing CRO activities
- 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 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 and web-based systems.
- Ability to travel <25% of time

Preferred Skills/Experience:

- Knowledge of respiratory clinical trials
- Experience with pediatric and/or rare disease clinical trials and international clinical trials

Other Information

• Anticipated Start Date: August 15, 2020

Qualified candidates please e-mail resumes with references to awoodring@parion.com