Company Overview

Saol Therapeutics (pronounced “Sail”) is a specialty pharmaceutical company focused on providing therapies to patients with unmet medical needs. The company has a strategic emphasis on spasticity and neurologic therapeutic areas. Our seasoned management team has a broad range of experience in commercialization, acquisition, licensing, formulation and product development. We are a dedicated group of professionals who have committed our life’s work to developing and bringing high-value, much-needed drugs to market. We are looking for highly-skilled individuals who are patient focused, passionate, ethical, team-oriented, and who want to help build a company that will make a difference in people’s lives.

Location

Roswell, Georgia

Manager

Director, Clinical Operations

Role Overview

The Clinical Project Coordinator will support Clinical Operations and Development activities related to clinical trial activities for products in the Saol development pipeline. The role will provide the necessary support to ensure successful implementation of all stages of a clinical trial, inclusive of start-up, execution, and closeout activities. Additionally, the Clinical Project Coordinator will provide the required support for other cross-functional development team members as required.

Responsibilities

- Provide general administrative support to the Clinical Operations and Development departments to ensure the most effective and efficient conduct of all clinical trials.
- Assist the clinical study teams in completion of all required tasks to meet departmental and project goals.
- Track the progress of a clinical trial including patient recruitment, trial supplies and trial documentation.
- Accountable for management of study materials and supplies, inclusive of ordering, tracking, storage, distribution, reconciliation and destructive (where applicable).
- Responsible for the preparation and management of study documentation, forms and development of filing systems and processes (e.g., Trial Master File, study tracking tools).
- Assist in the distribution of study documentation to investigators and site staff, inclusive of regulatory documents and safety data.
- Serve as the primary liaison between the study team members, CRAs and investigator sites and provide support with monitoring visit preparation and conduct.

- Communicate with and manage study sites to obtain regular updates specific to enrollment/recruitment status, provision and procurement of required trial documentation, fulfillment of study supply requests and other activities as required.
- Assist with organizing study meetings, preparation of meeting materials, and production of meeting agendas and minutes for study meetings.
- Assist in the coordination and tracking of Investigator and vendor payments.
- Develop, maintain, and reconcile all study Trial Master Files and ensure files are audit ready throughout the study.
- Solid working knowledge of ICH GCP guidelines and applicable regulatory requirements.
- Travel to study sites as needed to assist with conduct of monitoring visit activities (approximately 20% travel anticipated).
- Perform other responsibilities as may be required by Saol, consistent with a growing, dynamic company.

Qualifications

- Bachelor's degree preferred but not required, provided relevant work experience.
- Minimum 5+ years prior experience working in clinical research at sponsor or CRO.
- Strong organizational skills, detail oriented and able to effectively manage multiple tasks in a face paced environment.
- Strong oral and written communication skills.
- Proficient in the use of Microsoft office products, inclusive of Word, Excel, PowerPoint and Outlook.
- Ability to be flexible and adaptable in the face of evolving organizational priorities.
- Strong interpersonal skills and ability to work effectively with small teams with a wide range of varying stakeholders.
- Travel: US and International as needed (approximately 20%)

Successful Candidates Demonstrate Saol's Values

Trustworthy – We believe that the foundation of trust is truthfulness, transparency and fairness. These principles will be the basis for all our interactions.

Focused on Patients – We will anchor our decisions with full consideration of their impact on our patients, believing that in doing what is right for them serves a higher purpose.

Passionate – We enjoy working hard, but are not one-dimensional, being curious about the world around us and striving to be continuous learners who surround ourselves with others who inspire and challenge us.

Nimble – We embrace new and promising opportunities while adjusting quickly and efficiently to the inevitability of change.

Entrepreneurial – We create value through our focus on providing solutions, drive to deliver results, and our ability to work together in solving business challenges with integrity.

Compensation
Saol Therapeutics is prepared to offer a competitive salary, bonus, and equity, as well as career development opportunities.

Apply or Learn More – www.saolrx.com
Email resume to: HR@saolrx.com