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

Saol’s Roswell, Georgia office.

Manager

Senior Vice President, Technical Operations

Role Overview

The Clinical Director at Saol will have primary responsibility for the design, execution, completion and Regulatory submission support leading to registration for clinical development programs that are in Saol’s development portfolio. As a result, the Director will be responsible for establishment and monitoring of budgets and timelines, and will coordinate closely with other cross-functional development team members. In addition the role will also support Saol’s IST program activities and will be responsible for the establishment of supporting procedures and controls (and revisions thereto), as required to support the clinical activities compliant with the phase/stage of development. The Director should expect regular interaction with the Leadership Team, Board of Directors and Technical Advisors to the company, given the critical nature of the role.

Responsibilities

- Propose, design and defend clinical development programs aligned with development project objectives.
- Directly responsible for drafting and completion of study protocols, reports, submissions for publication, all other major written deliverables (regulatory submissions, original articles, abstracts), and other relevant documents as needed.
- Oversee activities relating to planning and execution of clinical studies.
- Develop clear and actionable Standard Operating Procedures or related documentation.
- Ensure adherence to SOPs and study-specific guidelines, GCP, and regulatory compliance with FDA and all other relevant regulatory bodies.
- Manage interaction and develop periodic update mechanisms for Saols IST programs.

- Create supporting reports/documents as required to aid Regulatory authorization submissions related to projects, participation at Regulatory Authority meetings as required.
- Interact with senior leadership on a regular basis to provide updates on progress of all programs, including challenges and changes to the program necessary to achieve regulatory authorization.
- Domestic and international travel to manage vendor selection/qualification/oversight and Saol partner relationships to maximize the success of the programs (approx. 35%).
- Support for due diligence/business development opportunity evaluations as required.
- Perform other responsibilities as may be required by Saol, consistent with a growing, dynamic company.

Qualifications

- Bachelor's degree in a technical field with a graduate degree preferably in a clinically related discipline (PhD, PharmD, MD, DO).
- 10 years+ clinical development experience in pharmaceutical, biotech or specialty pharma companies.
- Knowledge of a wide variety of vendor capabilities and prior contacts with established working relationships.
- Successful track record of building constructive relationships with all stakeholders and team members including management, peer-group, and cross – functional team members/reports
- Proven influencing skills with internal and external stakeholders.
- Excellent oral and written communication skills.
- Significant experience in the technical aspects of drug development (experience with drugs and biologics preferred).
- Knowledge and preferably direct experience with the regulatory submission process as relates to this role.
- Demonstrated prior clinical project management and negotiation skills.
- Ability to effectively present ideas and document complex medical and clinical concepts in both written and oral communications, with a keen eye for detail.
- Knowledge of submission requirements and procedures for scientific publications.
- Demonstrated ability to accurately gauge the urgency of an issue and proactively manage the actions required to make successful decisions within aggressive timelines.
- Highly effective interpersonal skills and the ability to continually demonstrate poise, tact, and diplomacy.
- Ability to multitask, prioritize, and manage time efficiently in a fast-paced and entrepreneurial environment.
- Prior experience with ISTs and their management.
- Direct clinical experience in the treatment of spasticity preferred.

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
Call and/or email resume to: HR@saolrx.com