Position Specification
Director of Regulatory

Company Overview

Saol Therapeutics (pronounced “Sail”) is a specialty pharmaceutical company focused on providing therapies to patients with unmet medical needs. Addressing the needs of patients with rare diseases and underserved neurological conditions are our passion and focus at Saol. Supporting patients with high unmet needs by offering promising treatment options is what drives us. 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 Director of Regulatory at Saol will have primary responsibility for the oversight and management of Regulatory matters related to Saol’s commercial and development product pipeline globally. In conjunction with that, the Director will be responsible for the establishment and monitoring of budgets and timelines, will coordinate closely with other cross-functional development team members, and will provide technical guidance and managerial oversight of the Regulatory team.

Responsibilities

- Provide the leadership on regulatory strategy and tactics contributing to the achievement of business objectives.
- Provide Regulatory direction related to registration requirements for development and commercially marketed products globally.
- Insure Regulatory support for development projects, project teams, and all regulatory submissions (PIND/IND/CTA).
- Maintenance of registrations and insuring regulatory compliance for Saol’s commercially marketed products.
- Responsible for insuring the regulatory review, evaluation, and recommendations related to change controls/change requests for Saol’s commercially marketed products.
- Establish relationships with Saol’s distribution partners, commercial manufacturing partners, and other key stakeholders, providing regulatory guidance and support as required.
- Lead the regulatory team to insure prioritized objectives are successfully delivered; team management and performance responsibilities.

- Support other cross functional groups as required, to assist in the achievement of business objectives.
- Maintain and utilize a strong working knowledge of regulatory requirements in commercially relevant geographies.
- Provide Regulatory review/oversight/guidance for advertising and promotion; regulatory review and submission process.
- Oversee activities relating to planning and execution of all regulatory submissions.
- Develop/review and insure adherence to SOPs as required to support regulatory compliance with FDA and all other relevant regulatory bodies.
- Provide inputs/recommendations and manage departmental Regulatory budget.
- Lead Regulatory Authority communications/interactions.
- Insure support and recommend process improvements for internal regulatory documentation/tracking/archival systems.
- Provide support for Regulatory Agency inspections, as required.
- Lead Regulatory planning/requirements/ preparation/submissions related to Regulatory Authority meetings, as required.
- 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.
- Domestic and international travel as required to establish/support vendor/ partner relationships to maximize the success of the programs (approx. 20%).

Qualifications

- Bachelor's degree in a technical field with a graduate degree preferred.
- 10 years+ regulatory experience in pharmaceutical, biotech or specialty pharma companies. US/Canada experience required, ROW experience preferred.
- Experience with pharmaceuticals and biologics preferred; medical device experience in addition a plus.
- 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.
- Experience in drug development (experience with drugs and biologics expected, devices a plus).
- Knowledge and direct experience with the regulatory submissions process, in particular electronic submissions.
- Demonstrated negotiation skills.
- 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.

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