



### **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, Regulatory Affairs

### **Role Overview**

The Manager will support regulatory activities related to both commercially marketed products, as well as those in the Saol development pipeline. The territory involves both US, Canada, and rest of the world (ROW) territories.

### **Responsibilities**

- Responsible for the creation/review of technical sections in support of regulatory submissions for assigned projects. This might include INDs/CTAs, ANDAs, NDAs, BLAs, and device combination products.
- Participate in team meetings/project discussions.
- Support preparation for Health Authority interactions including preparing meeting requests and briefing documents.
- Support the regulatory submissions process.
- Support the maintenance of internal regulatory tracking systems and archival systems. Identify opportunities for continuous system improvement.
- Create or review/edit SOPs or related process documents as required.
- Participate in the Labeling Review Committee or support the review/drafting of labeling and its revision as required.
- Establish relationships and support the communications with ROW distributors, in response to regulatory needs for Saol product distribution in their territory.
- Support the regulatory review and submission process related to advertising and promotion. Participate in the PRC process.
- Provide regulatory guidance and support as needed to Saol distribution partners and vendors.
- Review and evaluation/recommendations related to Change Controls; provide regulatory guidance in support of internal staff.

### **Qualifications**

- Minimum Bachelor's degree in a technical field. Graduate degrees preferred.
- Minimum 5+ years prior regulatory affairs experience in support of commercially marketed products and development products in pharmaceutical, biotech or specialty pharma companies. Experience with drugs and biologics preferred. Additional device experience a plus.
- Prior experience in advertising and promotion support preferred.
- Prior experience in US and ROW markets strongly desired.
- Excellent oral and written communication skills.
- Strong understanding of the drug development process.
- Strong knowledge of the regulatory requirements for pharmaceutical/biologic products. Additional experience with medical device products a plus.
- Knowledge of eCTD format and submission software systems preferred.
- Ability to be flexible as timelines or project priorities shift.
- Strong computer skills Experience in MS Word, Excel, Outlook and Adobe Acrobat
- Travel: US and International as needed (<25%)

**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](mailto:HR@saolrx.com)