Position Specification
Global Regulatory Affairs Labeling Specialist

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

Head of Global Regulatory Affairs

Role Overview

Has overall accountability for the initial creation and relevant updates to labeling documents for the product portfolio, development/establishment of processes related to labeling controls, communication of updates/status, support for Regulatory submissions related to labeling, communications and updates with Saols global distributors, and insuring updates to relevant Saol, distributor, or government labeling databases as required.

Responsibilities

- Prepares, tracks, maintains, reviews, and coordinates reviews for required labeling documents (e.g., physician’s label, patient insert, carton, label, etc.) and maintains change history for all labeling documents;
- Collaborates with contributing functional areas and external sources to verify accuracy of submission labeling components in the required formats. Advises on upcoming changes to labeling and provides guidance on when changes need to be implemented in the market;
- Leads the Labeling Team through the labeling development/review processes; clearly communicates requirements, deliverables, and required timelines;
- Partners with other members of the Labeling Team for the development/maintenance of Core Data Sheets (CDS), Core Safety Information (CSI), US Prescribing Information (USPI), Patient Package Inserts (PPIs), Product Monographs (PMs), Summary of Product Characteristics (SPC), Patient Information Leaflets (PIL), Canadian Product Monographs, and related elements, as required across the relevant territories for commercially marketed products and those going through late stage development;
- Approves and maintains artwork and labeling proofs for labeling components; Key Regulatory signatory on labeling authorization elements;
- Notifies appropriate groups of changes or recent source/reference labeling approvals;
- Prepares country-specific labeling; maintains country specific translation mastercopy to meet labeling responsibilities;
- Ensures all labeling supporting documentation and final approved labeling documents are appropriately archived and tracked;

- Initiates and approves final printed artwork on behalf of the country when needed for artwork changes and assists with timely implementation of the updated artwork in the market;
- Supports the end-to-end process to minimize the risk and associated costs of a significant error occurring in the final labeling preparation;
- Prepares labeling submission documents for FDA/international regulatory requirements including annual reporting requirements, such as NDC annual reporting and Drug Notification Forms (DNF) for Health Canada, review of spls for submission to the Office of the Commissioner (OC);
- Direct interface with vendors/partners as required to support labeling;
- Proactively identifies risks and issues, and provides recommended solutions;
- Maintains and updates processes related to labeling controls, creation, review, and revision;
- Leads labelling changes in support of new product launch activities.
- Keeping up to date with labeling guidelines and regulations as they relate to the development/maintenance of labeling documents, an understanding of regulatory labeling; requirements of relevant region or countries, and advises team members as appropriate;
- Communicates with team members when new revisions of labeling are put into effect, including coordinating the updates to agency websites and those websites maintained by Saol;
- Interfaces with International Distributors on commercial products to insure current labeling status, provide/obtain updates, insure updated Regulatory files and any corresponding websites as required;
- Collaborates with Regulatory and other team members in the development of new labeling text; identifying competitor labeling or other established precedents for awareness and consideration;
- Maintains awareness of current and new tools, technologies, and processes to support efficient global label development and corresponding submissions and approvals and makes recommendations for the acquisition of tools to improve efficiencies;
- Establishes and maintains systems in support of labeling revision history status across markets/territories and periodic reviews thereof; and
- Collaborates with Saol distributor partners regarding labelling elements, revisions, and related updates.

Qualifications

- Minimum Bachelor's degree preferred in sciences with minimum 3-5 years labeling experience and pharmaceutical Regulatory experience.
- Excellent command of language (English) and professional knowledge of medical terms; Technical writing skill proficiency.
- Ability to establish relationships and work across multiple cultures and locations
- Good communication and organizational skills and a meticulous eye for details
- Good understanding of pharmaceutical or medical terminology
- Proficiency in standard office technology, including Microsoft Suite, Outlook Mail/Calendar; willing to learn additional applications as needed
- Experience working on multi-disciplinary teams and projects
- Good knowledge of rigorous pharmaceutical and/or scientific documentation practices and change control processes (e.g. revision control)
- Knowledgeable on key labeling requirements worldwide
- Proven understanding of related core labeling documents (CDS,CSI, etc.)
- Ability to work well in cross-functional teams, exhibiting a combination of active listening skills and the confidence to guide decision-making for the document content strategy, as well as interacting effectively with all levels/roles of project team members
- Project management skills encompassing good communication skills, ability to negotiate, and influence/problem solving capability.

- Registration experience associated with development, maintenance and commercialization activities within Regulatory Affairs (drugs and biologics); Experience at the country level outside of US is important and advantageous.
- Ability to interpret and apply global and local regulatory guidance around labeling and associated supportive documentation, both in the pre-approval and post approval (maintenance) stages.
- Evaluate the impact of a label change on associated labels and manufacturing operations.

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