



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

Dublin, Ireland

Manager

Product Development Director

Role Overview

Saol is currently developing products through late-stage development and regulatory filings. This role will play a key part of coordination and assisting the management of development programs to achieve milestones on-time and on-budget. The skillsets associated with this role include expertise in development program project management, CMC expertise including analytical, formulation, manufacturing and technical writing to support development reports and required regulatory authorizations. Additional experience in bioanalytical method development and validation is a plus.

Lastly, this role will ultimately take responsibility for analytical direction and assisting contract development and manufacturing organization in the development of a robust analytical program to support development and commercialization of Saol’s product development portfolio.

Responsibilities

- Assist in the coordination and management of product development portfolio and process to ensure budgets and timelines are met. Prepare periodic updates to Saol management.
- Assist in the identification of external vendors or internal partner organizations to enable the most efficient and effective process to complete development.
- Responsible for the analytical/bioanalytical development and validation programs supporting product development portfolio across chemistry, non-clinical and clinical programs.
- Support commercial pipeline by assisting QA during technical investigations and define appropriate corrective and preventative actions when required.

- Assist in technical solutions for formulation development, manufacturing and other CMC related items.
- Preparation of Product development SOPs, guidance documents and technical reports.
- Create supporting reports/documents as required to aid Regulatory authorization submissions related to projects
- Interact with cross functional stakeholders on a regular basis to provide updates on progress of all programs, including challenges and changes to the program necessary to reach approval.
- Perform vendor assessment and selection to support product development portfolio. This responsibility will also require vendor audit support if requested.
- Domestic and international travel to manage vendor relationships and Saol relationships to maximize the success and speed of the programs.

Qualifications

Bachelor's degree in a technical field. Graduate degree strongly preferred.

- 6 years+ product development experience in pharmaceutical, biotech or specialty pharma companies
- Knowledge of a wide variety of vendor capabilities and prior contacts and working relationships already established
- Strong and proven technical and interpersonal skills
- Successful track record of building constructive relationships with functional stakeholders and team members including management, peer-group, and cross – functional team members/reports
- Excellent oral and written communication skills
- Significant experience in the technical aspects of analytical and drug development
- Knowledge of the FDA/ICH regulatory requirements to obtain approval for pharmaceutical and medical device products
- Project management skills to include day to day running of program activities, keeping program on time/budget and escalating risks/opportunities when arise to Manager.
- Demonstrated ability to accurately gauge the urgency of an issue and proactively manage the actions required to make successful decisions within aggressive timelines
- Demonstrated good judgment and capable of solving complex problems
- Willingness and appetite for travel

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.



**Position Specification
Manager, Analytical & Formulation Development**

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, as well as career advancement opportunities.

Apply or Learn More

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