Operations Process Lead

Saol Therapeutics (pronounced “Sail”) is an international specialty pharmaceutical company focused on providing therapies to patients with unmet medical needs. The company has a strategic emphasis on CNS/Neurology and orphan therapeutic areas. The 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 seeking a highly-skilled individual who is patient focused, passionate, ethical, team-oriented, and who wants to grow a company that will make a difference in people’s lives.

SUMMARY
Responsible for the direct management of activities related to manufacturing process operations, including process validation and technology transfer programs between Saol and any identified Saol third party CDMO vendors.

LOCATION
Position can be based in Roswell, GA or Dublin, Ireland

REPORTS TO
Quality Director

ESSENTIAL FUNCTIONS:

- Establish a new functional capability within the organization, creating the supporting processes/systems and documentation elements essential to the transitioning of products from development into commercial production scale and the technical transfer activities associated with moving products/projects from one facility/site/company to another.
- Identify and execute the specific project plans required to insure the successful transitioning of products/projects; establishing timelines, budgets, key deliverables, and communications for organization visibility.
- Provide technical support for Regulatory Authority audits/inspections related to product/project transfers/scale up/validation.
- Create process validation plans/executional strategy and final process validation reports related to product/project transfers/scale up/product commercialization.
- Provide solutions which are robust, GMP compliant and will withstand regulatory inspection scrutiny.
- Establish formalized, functioning, and strong relationships with CMO/CDMO transfer teams
- Build strong working relationships with internal Saol stakeholders such as QA, Regulatory Affairs, Development, and Finance.
- Define, document and establish controls for technology transfer and knowledge management; identify continuous improvement activities to improve performance.
- Manage external and internal organizational resources to achieve the requirements of the project plan.
- Apply expertise and technical knowledge to support the progression of assigned projects. Continue to learn/advance learnings to the benefit of the projects.
- Manage and approve the change management process, as needed to support the product/project transfers and related activities.

KNOWLEDGE AND SKILL REQUIREMENTS:

- Minimum of 5- 10 years' experience working within a process qualification / technology transfer environment, with a proven track record with biologcs and sterile fill finish
- Minimum Bachelors degree in Engineering or Science .
- Demonstrated experience in pharmaceutical/ biologics process validation/tech transfer activities
- Demonstrated experience in the management of projects, with successful outcomes.
- Experience in process, equipment, analytical qualification.

- Experience in process validation/ process validation documentation and reporting.
- Experience in the concepts and applications of quality by design concepts and practices
- Demonstrated experience in applying risk management processes
- Experience with biological and / or sterile production environments
- A well developed understanding of cross functional relationship between process transfer/ qualification, QA and Regulatory Affairs.
- An ability to work independently across different departments.
- Excellent organizational skills
- Excellent oral and written communication skills; technical writing capability.
- Strong knowledge of quality systems and regulatory requirements across US/EU authorities.
- Strong technical and problem-solving skills/experience.

PREFERRED SKILLS AND EXPERIENCE:

- Comfortable working in a dynamic changing environment with a multidisciplinary team
- Experience in virtual / third party manufacturing environments
- Regulatory Authority inspectional experience; defense of project/validation initiatives.

TRAVEL REQUIREMENTS:

25 to 30%(including but not limited to Europe and North America)