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 CNS Disorders and Rare Disease 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, GA (US Headquarters)

Role Overview

The Director of Quality will manage and lead the development, implementation, and continuous improvement of the Quality Management System (QMS) for molecular diagnostic medical devices. This role ensures compliance with global regulatory standards (e.g., FDA 21 CFR Part 820, ISO 13485, GCP) and supports product development, manufacturing, and post-market activities.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

Quality Systems

- Strategic Leadership:
  - Develop and implement quality strategies aligned with commercial and development goals.
  - Serve as the quality lead for cross-functional teams including R&D, Regulatory Affairs, Manufacturing, and Supply Chain.
- Quality Systems Oversight:
  - Maintain and improve Quality Management Systems (QMS) in compliance with cGMP, ICH, FDA, EMA, and other global regulatory standards.
  - Oversee document control, change management, CAPA, deviation management, and training systems.

Pharmaceuticals

- Product Development Support:
  - Provide quality oversight during clinical development and manufacturing activities.
  - Review and approve CMC documentation for regulatory submissions were required.
- Commercial Operations:
  - Ensure quality compliance of contract manufacturer and contract service organisations (CMO,CSO).
  - Ensure oversight of CSOs engaged in Good Distribution Practices

Medical Device

- Maintain Design History files
- Ensure effective risk management and design control processes are in place for diagnostic products.
- Vendor management oversight of CMOs/ CSOs

GCP

- Develop, implement, and maintain GCP quality systems and SOPs.
- Conduct internal and external audits (e.g., investigator sites, CROs, vendors).
- Provide GCP compliance guidance to clinical teams and stakeholders.

KNOWLEDGE AND SKILL REQUIREMENTS:

- Demonstrated skills and experience in the conduct of Quality activities as described above in support of medical device, pharmaceutical both in commercial and development sphere
- Demonstratable experience in autonomous and collaborative team environments.
- Initiative, creativity, and the ability to manage change and work effectively in a complex, rapidly changing environment.
- Strong communication skills and multi-tasking capabilities
- Ability to navigate cross functionally and strategically leverage relationships to achieve business results both with internal and external stakeholders.
- Knowledge of quality standards and regulatory guidelines and requirements relating to medical device and pharmaceuticals.
- Highly motivated, intelligent individual with strong project management, analytical, problem solving and interpersonal skills
- Demonstrate high ethical and professional standards, and demonstrates company values consistently with all customers and business partners
- Excellent collaboration skills to optimize the relationship with internal and external partners.

PREFERRED SKILLS AND EXPERIENCE:

- Bachelor's or Master's degree in Life Sciences, Engineering, or related field.
- 10+ years of experience in quality roles within the pharmaceutical , medical device, or diagnostics industry.
- 2+ years in a director-level or equivalent demonstratable leadership role.
- Strong knowledge of Good distribution practices for pharmaceuticals and molecular diagnostics technologies and regulatory requirements.
- Experience with ISO 13485, FDA 21 CFR Part 211 & 820 , and risk management (ISO 14971) Good Clinical Practices compliance regulations and standards.
- Proven track record of successful regulatory inspections and audits.

Travel Requirements

- Ability to travel required. Anticpated travel 20-25%.

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
Position is a contracted role, with potential to move to a full-time role.

Apply or Learn More
Call and/or email resume to: HR@saolrx.com