Soleno Therapeutics
Job Description

Job Title:	Reports To:	Date Created:
Associate Director / Director, Regulatory Affairs	**Vice President, Regulatory Affairs**	**January 27, 2024**
Department: **Regulatory Affairs**	**Job Type:** ☒ Full-time ☐ Part-time ☐ Contractor	

SUMMARY OF JOB (brief description): Soleno Therapeutics, Inc., based in Redwood City, California, is a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases. We are seeking a highly motivated and enthusiastic individual to join Soleno Therapeutics' growing regulatory affairs group. Together with the Regulatory Affairs team and in close collaboration with other departments at Soleno Therapeutics, the Associate Director / Director, Regulatory Affairs will take a hands-on approach to developing and implementing regulatory strategies for our development programs in rare diseases. The Associate Director / Director, Regulatory Affairs will be based at our office in Redwood City, CA in a primarily hybrid work environment to foster a strong team and collaborative dynamic.

RESPONSIBILITIES:

- Responsible for strategic and operational regulatory input and support for collaboration with other project team members, including regulatory team members.
- Contributes to the development of regulatory plans and strategies, identifies and proposes risk mitigation strategies, and influences project teams and sub teams across international site locations.
- Assist in developing and implementing strategies for the earliest possible approvals/clearance of regulatory submissions associated with assigned projects.
- Prepares and/or manages submissions that may be technically complex and require extensive interaction with departments outside of regulatory affairs.
- Provide regulatory advice and information to cross-functional teams and to other functional areas (i.e., CMC, nonclinical, and clinical) for product development and planning to support the timely achievement of company and department goals.
- Leads the drafting, review, and finalization of responses to queries from Regulatory Authorities
- Maintains knowledge of regulatory requirements up to current date and communicates changes in regulatory information to other departments.

QUALIFICATIONS:

- A degree in a life science, chemistry, or chemical engineering or closely related discipline with a graduate degree preferred and at least 10 years of experience in pharmaceutical regulatory affairs, that includes, but cannot be limited to, CMC regulatory affairs. Strong track record of contributing

to regulatory submissions would be considered. Experience in a small company and in a fast-paced environment is preferred.

- Proven proficiency in MS Word, Excel, Power Point, Visio, Adobe Acrobat. Must have experience with document formatting templates.
- Regulatory experience development of modified-release solid oral dosage forms is highly preferred, and regulatory experience in the development of small molecules is required.
- Established track-record of drafting, reviewing, and finalizing successful regulatory submissions and Regulatory Authority interactions as required. Recent NDA experience from late phase 3 study, pre-NDA meeting, NDA preparation through product approval is a plus.
- Proven ability to manage multiple complex projects, with the flexibility and adaptability to re-prioritize workload.
- Excellent verbal, written, negotiation and interpersonal skills are required. Must be articulate and able to communicate effectively both orally and in writing with employees at all levels of the global organization and external audiences.

Salary Range:

Associate Director: $170,000 - $215,000

Director: $190,000 - $250,000

Please submit resumes to Soleno Therapeutics, Inc. at hr@soleno.life.