Soleno Therapeutics
Job Description

Job Title:	Reports To:	Date Created:
Associate Director / Director, CMC 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, enthusiastic, and experienced regulatory professional to join Soleno Therapeutics as to join the growing regulatory affairs group. The Associate Director / Director, CMC Regulatory Affairs, together with the VP, Regulatory Affairs, will be responsible for taking a hands-on approach to developing and implementing regulatory strategies for CMC aspects of our development programs in rare diseases. This will be accomplished in close collaboration with other departments within Soleno Therapeutics. The Associate Director / Director will be based in 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 CMC collaboration with other project team members, including regulatory team members.
- Plan, coordinate, and develop high quality and compliant CMC sections / information for regulatory submissions. This may include, but may not be limited to, the drafting, reviewing and/or approving of CMC sections of key regulatory submissions (e.g., IND information amendments, IMP Dossier [IMPD] updates, clinical trial applications, NDA/MAA module 3 and QOS), reviews of CMC protocols and/or reports; review and approval of CMC information in Investigator's Brochures, clinical and/or nonclinical protocols and/or reports, Investigational Medicinal Product (IMP) labeling, meeting requests, and meeting briefing documents.
- Provides 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 submission and/or responses to CMC queries from Regulatory Authorities.
- Collaborate with CMC and Quality to develop and execute plans and strategies required for Scale-up and Post-Approval Changes and draft, review, finalize submissions for these changes.
- Contributes to the development of regulatory plans and strategies and proposes risk mitigation strategies, as requested by the department head.

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QUALIFICATIONS:

- A degree in a life science or closely related discipline with a higher degree preferred (e.g., MSc, MPH, PhD). A minimum of 7 years and 10 years direct pharmaceutical / small molecule regulatory affairs is required for the Associate Director and Director positions, respectively, in CMC Regulatory Affairs. Experience in a pharmaceutical or biotech company from IND through late-stage development is required. Experience in a small company and hands-on NDA experience from preparation through submission and approval for a modified-release, solid oral dosage form in a non-oncology, rare disease indication is strongly preferred.
- Regulatory experience with modified-release solid oral dosage forms is highly preferred.
- 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, NDA preparation through product approval and commercialization a plus.
- Proven ability to manage multiple complex projects, with the flexibility and adaptability to re-prioritize workload.
- Strong experience interacting with the FDA at Type B (i.e., Pre-IND, End-of-Phase 2, Pre-NDA) and Type C meetings.
- Proven proficiency in MS Word, Excel, Power Point, Visio, Adobe Acrobat. Must have experience with document formatting templates.
- Must be a hands-on team player who thrives in a fast-paced, team environment.
- 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 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.