

Job Description
Manager to Director, Regulatory Affairs

Soleno Therapeutics, Inc. (Soleno) is seeking an experienced regulatory professional to be a part of our Regulatory Affairs department. This individual will report to the Vice President, Regulatory Affairs.

Primary Responsibilities:

- Provide ongoing regulatory support Clinical, CMC, and Quality to address regulatory issues and questions
- Develop and provide oversight for development of key regulatory submissions including INDs, CTAs, NDAs
- Author and manage the development of high-quality regulatory documents and submissions that may include, but not be limited to: INDs, CTAs, NDAs, submission amendments, meeting requests, briefing documents/meeting packages, requests for designation, and general regulatory correspondence with health authorities
- Review protocols, reports, and other development-related documents across all development areas (i.e., quality, safety, efficacy)
- Review and provide regulatory and development input into clinical protocols, investigator brochures, study reports, and submission-level documents

Qualifications:

- Degree in a Life Science or a related discipline with a higher degree preferable (e.g., PhD, PharmD, MSc, MPH) and a minimum of 5 years of regulatory affairs experience for a manager position; title commensurate with number of years relevant experience. Small company experience is highly preferred. Hands-on experience in late-stage development through NDA approval in non-oncology, rare disease indication(s) is strongly preferred.
- An established track-record of successful regulatory submissions is required. Recent NDA submission experience is a plus.
- Proven ability to manage complex projects, with the flexibility and adaptability to re-prioritize workload to meet changing timelines
- Must be a hands-on team player accustomed to working in a fast-paced environment
- 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

Other Information

- Interested applicants please send resume to hr@soleno.life.