Job Description

Job Title: Medical Director	**Reports To (Title):** Senior Vice President, Clinical Development	**Date Created:** **11 December 2023**
Department: Clinical Development	**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. The Sr./Medical Director will be responsible for the clinical development of the company's drug candidate(s). The Sr./Medical Director must have a strong understanding of all phases of clinical drug development, including clinical trial management, IND and NDA submissions, medical monitoring, pharmacovigilance, GCP principles, and have extensive experience collaborating with Clinical Operations, Biometrics, Regulatory Affairs, Medical Affairs, and key external stakeholders.

RESPONSIBILITIES:

- Develop and implement clinical strategies to support the company's rare disease program(s), ensuring alignment with overall corporate objectives.
- Lead in the design and execution of clinical development plans, including the planning and hands-on execution of clinical trials.
- Work cooperatively with Clinical Operations, CROs, and external vendors to implement clinical studies (e.g. lead from study start-up through database lock; review and draft start-up documents/study manuals; perform ongoing data review/analyses; and draft and present clinical information to Investigators and advisory panels as required).
- Provide clinical leadership and strategic medical input for all clinical deliverables. Clinical deliverables may include, but are not limited to, protocols, statistical analysis plans, regulatory documents/registration dossiers, and scientific publications.
- Lead in the development of the clinical sections of all regulatory documents in support of submissions, including INDs, NDAs, urgent information requests, and other submission packages to global health authorities, as required.
- Function as medical monitor and internal subject matter expert, ensuring the overall safety of drug candidate(s), while supporting pharmacovigilance functions (e.g., IND safety updates, Drug Safety Update Reports [DSURs], and other safety updates)
- Actively seek and maintain credible relationships with Key Opinion Leaders (KOLs), Investigators, and patient advocacy groups.
- Other duties commensurate with position and experience, as assigned.

QUALIFICATIONS:

- Board certified/board eligible physician (e.g. MD, DO) with a minimum of 5 years of biopharmaceutical industry experience, with experience in the successful execution of clinical development plans.
- Demonstrated ability to independently evaluate, interpret and present complex clinical and scientific data.
- Demonstrated ability to critically evaluate complex drug development programs.
- Rare/orphan disease experience desired.
- Team player with proven leadership experience.
- Demonstrated ability to work within a fast-paced, multi-disciplinary team of peers and outside experts.
- Excellent communication, presentation, and interpersonal skills.

Salary Range: $250K - $300K