Job Description

Job Title: Head of Medical Writing (Director level)	**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 Head of Medical Writing will be responsible for providing leadership and strategic direction to the medical writing function at Soleno, ensuring the timely delivery of accurate and effective documents for regulatory submissions, clinical studies, clinical/scientific publications, and company presentations. This role requires an experienced professional with a strong background in medical writing, regulatory affairs, and clinical development, and a commitment to maintaining the highest standards of quality and compliance.

RESPONSIBILITIES:

- Develop and implement a strategic plan for the company's medical writing activities, ensuring alignment with clinical development, regulatory affairs, and overall business goals.
- Directly contribute to cross-functional teams to integrate medical writing activities into overall project plans.
- Lead in the development and preparation of high-quality regulatory documents, including clinical study reports, protocols, investigator brochures, and submission documents (e.g., INDs, NDAs, urgent information requests, etc.).
- This role will be responsible for coordinating the review cycles of documents, managing all aspects of document development, and leading the project teams through the process, including any discussions on document revision, QC, and finalization.
- Collaborate with clinical development, regulatory affairs, biometrics, and related cross-functional teams to gather and integrate data into regulatory documents.
- Actively participate in project team meetings to provide medical writing expertise and ensure timely delivery of documents.
- Evaluate and enhance medical writing processes and standards to optimize efficiency and quality.
- Stay current on industry best practices, regulatory guidelines, and technical advancements, as they pertain to medical writing.
- Ensure that all documents comply with regulatory guidelines and quality standards.

QUALIFICATIONS:

- Advanced degree in a relevant scientific or healthcare-related discipline (e.g., PhD, PharmD, MS, or equivalent).
- Minimum of 10 years of experience in medical writing within the biopharmaceutical industry.
- Experience in rare/orphan disease drug development desired.
- Experience leading/managing a medical writing team, including full-time or contract writers.
- In-depth knowledge of regulatory requirements, including ICH guidelines.
- Excellent communication, interpersonal, and project management skills.

Salary Range: $225K - $275K