Job Description

Job Title: Director, CMC Analytical Development	Reports To (Title): Vice President, CMC	Date Created: 06/13/24
Department: CMC	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 an experienced and visionary Director, CMC Analytical Development to lead our analytical development function. The successful candidate will play a pivotal role in overseeing analytical activities related to drug substance and drug product, ensuring the highest standards of quality and regulatory compliance. This role is critical in advancing our pipeline of therapies for rare diseases.

RESPONSIBILITIES:

- Develop and implement comprehensive CMC analytical strategies to support drug development and regulatory submissions.
- Collaborate with VP, CMC to ensure alignment of analytical activities with company goals and regulatory requirements.
- Lead the development, validation, and implementation of analytical methods for drug substances and drug products.
- Ensure the integrity, accuracy, and compliance of analytical data.
- Ensure all analytical activities comply with regulatory requirements (FDA, EMA, etc.) and industry standards.
- Prepare and review CMC analytical sections of regulatory submissions, including IND, BLA, NDA, and MAA.
- Prepare for and develop data-driven responses to regulatory requests for information related to analytical activities.
- Represent the company in regulatory interactions and inspections related to analytical activities.
- Manage analytical project timelines, budgets, and resources to ensure on-time delivery of milestones.
- Coordinate with cross-functional teams, including R&D, quality, regulatory, and clinical, to support CMC analytical activities.
- Stay current with advancements in analytical technologies and methodologies.
- Implement new technologies and best practices to enhance analytical capabilities and efficiencies.
- Other duties as assigned.

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QUALIFICATIONS:

- Master's degree or Ph.D. in chemical engineering, chemistry, organic chemistry, or a related scientific discipline.
- Minimum of 7-10 years of experience in CMC analytical development, with small molecule experience a must and a focus on modified release products preferred.
- Strong background in outsourced DS clinical development through commercialization is required, as is experience in outsourced development through commercialization of solid oral dosage forms, modified-release formulations, and pediatric formulations.
- Substantial experience in managing US CRO/CMOs for the analytical activities associated with the manufacture of cGMP DSs and DPs; experience collaborating with International CROs/CMOs a plus.
- Knowledge of GMP quality systems.
- Must possess a strong project leadership presence with excellent organizational skills and strong attention to details; excellent written and verbal communication skills.
- Must possess strong technical judgment; a problem solver with the ability to successfully and proactively identify and manage potential risks across all relevant areas.
- Strong knowledge of regulatory requirements and guidelines for drug development and analysis.
- Excellent leadership, communication, and interpersonal skills.
- Ability to work effectively in a fast-paced, dynamic environment.
- Ability to travel as needed.

Salary Range: $200k - $245k (Actual salary at the time of hire may vary and may be above or below the range based on various factors, including, but not limited to, the candidate's relevant qualifications, skills, and experience, as well as the location where this position may be filled.)

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