Job Description

Job Title: Senior Director, CMC	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 a highly experienced and motivated Senior Director, CMC to join our dynamic team. The successful candidate will play a critical role in leading and overseeing CMC activities related to drug substance and drug product development, manufacturing, and supply chain. This role requires deep expertise in small molecules pharmaceutical development and commercialization and a strong understanding of regulatory requirements for rare disease therapeutics.

RESPONSIBILITIES:

- Lead the development, optimization, and scale-up of drug substance and drug product processes ensuring robust and scalable manufacturing processes are in place for clinical and commercial production.
- Ensure all CMC activities comply with regulatory requirements (FDA, EMA, etc.) and industry standards.
- Lead the implementation of supply chain resources, partners, and procedures related to commercialization of Soleno products.
- Assist in the preparation and review of CMC sections of regulatory submissions, including IND, BLA, NDA, and MAA.
- Represent the company in regulatory interactions and inspections related to CMC activities.
- Technical oversight and management of Contract Manufacturing Organizations (CMOs) for process optimization, cGMP manufacture and supply of Drug Substance (DS) and Drug Product (DP) in support of ongoing clinical programs through commercialization.
- Ensure robust, scalable, efficient, cost-effective manufacturing of drug substance and drug product through commercialization.
- Establish and maintain strong relationships with external partners, including CMOs, CROs, and suppliers.
- Negotiate contracts and manage external vendors to ensure high-quality deliverables.
- Perform demand planning, project execution, supply chain management, and budget management.
- Define and implement external manufacturing policies, business processes, and systems.
- Coordinate cross-functional teams, including R&D, quality, regulatory, and clinical, to support CMC activities.

- Prepare contingency plans as appropriate and communicate issues, risks, and proposed mitigation plans; execute agreed upon plans in a timely manner.
- Mentor and develop team members, providing guidance and support for professional growth.
- Other duties as assigned.

QUALIFICATIONS:

- Master's degree or Ph.D. in chemical engineering, chemistry, organic chemistry, or a related scientific discipline.
- Minimum of 10-15 years of experience in CMC drug substance or drug product development and manufacturing, with small molecule experience a must and a focus on commercialization of rare disease products preferred.
- Strong background in outsourced drug substance 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 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 manufacturing.
- Excellent leadership, communication, and interpersonal skills.
- Ability to work effectively in a fast-paced, dynamic environment
- Ability to travel as needed.

Salary Range: $230k - $270k (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.