Soleno Therapeutics
Job Description

VP, CMC

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 motivated leader to join Soleno Therapeutics as Vice President, CMC. This role will be responsible for leading all CMC-related activities from process development through commercialization. The ideal candidate will be a seasoned pharma/biotech leader with an outstanding record of accomplishment in commercial manufacturing of biologics, quality, process development and supply chain. They will also have experience in the submission and maintenance of CMC sections of regulatory submissions and all stages of commercialization.

RESPONSIBILITIES:

- Oversee and provide technical leadership, strategic direction, risk assessment and oversight for translation of the corporate strategy into supportive strategies for national pharmaceutical manufacturing, quality control, process development, analytical development, technology transfer and validation.
- 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.
- Together with CMOs, develop and execute plans for the validation of DS and DP as required by cGMP, and other relevant legislation, regulations, and guidelines of the FDA.
- Perform demand planning, project execution, supply chain management, and budget management.
- Define and implement external manufacturing policies, business processes, and systems.
- Prepare contingency plans as appropriate and communicate issues, risks, and proposed mitigation plans; execute agreed upon plans in a timely manner.
- Author, review and/or approve CMC documents related to INDs, CTAs, NDAs, MAAs and/or other required regulatory submissions.
- Serve as primary CMC representative at key meetings with regulatory agencies.
- Other duties as assigned.

QUALIFICATIONS:

- Master's degree or Ph.D. in chemical engineering, chemistry, organic chemistry, or a related scientific discipline.
- Minimum of 20 years' experience. Experience must include small molecules in a pharmaceutical or biotechnology environment while overseeing CMC responsibilities in all stages from pre-clinical to commercialization.

- 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 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.
- Successful track record of developing collaborative, productive relationships across all functions and levels both internally and externally and the ability to manage and gain support of multiple stakeholders.
- Must possess strong technical judgment; a problem solver with the ability to successfully and proactively identify and manage potential risks across all relevant areas.

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