Vice President, Technical Operations

Soleno Therapeutics, Inc., based in Redwood City, California, is a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases. The Vice President, Technical Operations will be responsible for leading all CMC-related activities from process development through commercialization.

Responsibilities:

- 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.
- 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 all 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

Qualifications:

- Master's degree or Ph.D. in chemical engineering, chemistry, organic chemistry, or related scientific discipline. At least 18 years' experience with a Master's degree or at least 15 years' experience with a Ph.D.; experience must include clinical development through commercialization of small molecules.
- 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.
- Successful track record of developing collaborative, productive relationships across all functions and levels within and external to the company.
- Strong project leadership, customer service, problem solving, written and verbal communication skill required.

Please submit your current CV to Soleno Therapeutics at hr@soleno.life.