Soleno Therapeutics
Job Description

Job Title: Senior Manager, Quality Control and Analytical Development	**Reports To (Title):** Vice President, Quality	**Date Created:** 25 Jan 2023
Department: Quality	**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 motivated, individual to join Soleno Therapeutics as a Senior Manager, Quality Control and Analytical Development. The position is responsible for leading and managing Analytical Development and Quality Control operations for pre-commercial and commercial drug product and drug substance. Responsibilities include overseeing analytical method development, release testing, stability programs, methods transfers, and validations at external laboratories and Contract Manufacturing Organizations (CMOs). The position will manage critical assay, dissolution, and other methods development, analytical review of SOPs, test methods and specifications for raw materials/intermediates/drug substance/drug product, development/verification reports, validation protocols/reports, method transfers, COAs and stability summaries.

RESPONSIBILITIES:

- Support analytical activities associated with the company's programs.
- Work closely with CMC, QA, Regulatory, and external CROs/CMOs/Contract Laboratory collaborators to rapidly advance programs (small molecule, OSD) to key decision points, in preparation of regulatory submissions, approvals, and post-approval commitments.
- Provide critical, detailed review of external CROs/CMOs/Contract Laboratory test methods, verifications, validations, transfer protocols and developmental reports.
- Review lot release/stability analyses and investigations on critical raw materials, drug substance and drug product for various techniques (HPLC, GC, Dissolution, Titration, etc.) according to protocols, specifications, analytical methods, and procedures.
- Provide in depth technical and scientific advice and guidance to contract service providers and analysts in Quality Control operations. This advice includes external laboratory guidance on investigations, deviations, and trend analysis.
- Develop, establish, and implement quality control processes, specifications, validation, reports, etc. both internally and externally to support Soleno's commercial programs.
- Ensure testing and release services are provided in support of established schedules by being the primary technical and project management liaison with counterparts at the CMOs and contract laboratories.
- Assist in authoring and review of regulatory submissions and support internal, external audits, and regulatory inspections.
- Support the Quality group's efforts of compliance with the quality systems such as change control, quality investigations, CAPA resolutions in corrective action, audits, and any other recommendations to compliance issues and/or observations as they arise.
- Participate in cross-functional activities.

QUALIFICATIONS:

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- BA/BS or MA/MS in Analytical Chemistry or equivalent with appropriate work experience for both drug substance and drug product analytical development and quality control.
- Minimum of 10 years pharmaceutical industry experience in drug product development and analytical related activities with 5-7+ years demonstrated leadership and laboratory management skills.
- Excellent knowledge of analytical techniques, especially HPLC, GC, solid state, physical testing, and dissolution.
- A minimum of 3-year experience in stability testing of drug substance and drug product. Excellent knowledge of ICH guidelines for stability testing of pharmaceutical products.
- Excellent knowledge of analytical method development and validation.
- Prior experience related to managing external CMOs/Contract Laboratories.
- Working knowledge of pharmaceutical cGMPs and cGLP (US and EU).
- Must understand industry standards of practice for the analysis of pharmaceutical products.
- Recent experience in preparation/review of CMC sections of US or EU regulatory filing is desirable.
- Superior communication skills (both written and oral) are essential. Demonstrated ability to contribute successfully in a multi-disciplinary team environment.
- Must have hands on experience in managing diverse project activities with pharmaceutical manufacturing/testing facilities at different geographical locations.
- Strong project management experience with cross-functional team leadership and participation skills.
- Demonstrated ability to successfully work with and influence contract manufacturing/testing partners while maintaining a positive working relationship.
- Proficient with MS Office and laboratory systems.

Salary Range: $140k - $190k

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

SOLENO THERAPEUTICS