Soleno Therapeutics
Job Description

Job Title: Assoc Director/Director Quality Assurance Operations	**Reports To (Title):** Vice President, Quality	**Date Created:** 13 Feb 2024
Department: Quality	**Job Type:** ☒ Full-time ☐ Part-time ☐ Contractor	

SUMMARY OF JOB (brief description): Soleno Therapeutics, Inc., based in Redwood City, California, is a late 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 an Associate Director/ Director, Quality Assurance Operations. This position will collaborate with CMC, Regulatory Affairs, Clinical Operations, and Quality Systems to provide support and oversight to manufacturing and testing (clinical and commercial) sites to ensure that products are produced and tested in compliance with applicable regulations, legislation, guidelines, and Soleno requirements.

RESPONSIBILITIES:

- Provide quality direction and oversight of third-party manufacturing activities, ensuring compliance with cGMP, regulatory requirements and Soleno quality standards.
- Responsible for the lot review and disposition of all commercial and clinical products produced at third-party contract manufacturing organizations.
- Review and approve contractor master batch records, executed batch records, deviations, change controls and validations.
- Lead and support investigations into manufacturing discrepancies, deviations, and non-conformities, ensuring thorough root cause analysis and effective corrective and preventive actions (CAPAs).
- Assess the impact of proposed changes on product quality requirements.
- Assist with the management of the supplier quality program including performance of external supplier audits, risk ranking, supplier qualification and remediation. May assist in drafting and negotiating Quality Agreements.
- Responsible for the collection and presentation of quality metrics related to the quality oversight activities.
- Collaborate cross-functionally with CMC, Regulatory Affairs, and other departments to facilitate effective communication and resolution of quality-related issues.
- Identify opportunities for process improvements and efficiencies within the QA Operations function, driving continuous improvement.
- Report and escalate significant quality observations/risks to Quality Management.

QUALIFICATIONS:

- BA/BS degree with a minimum of 12 years' experience in the pharmaceutical industry (oral solid dose preferred), including at least 8 years in a quality assurance operations role.

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- Thorough knowledge and understanding of cGMP and relevant (EU and US) regulations, legislation, and pharmaceutical manufacturing industry standards for pharmaceutical manufacturing.
- Superior communication skills (both written and oral) are essential. Demonstrated ability to contribute successfully in a multi-disciplinary team environment.
- Demonstrated ability to successfully work with and influence contract manufacturing/testing partners while maintaining a positive working relationship.
- Working knowledge of health authority inspections and inspection readiness activities.
- Experience coordinating and conducting audits of CMOs and CTLs.
- Proven proficiency in MS Word, Excel, Power Point, and Adobe Acrobat.
- 10% travel is expected.

Salary Range: $170k - $250k (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.