Soleno Therapeutics
Job Description

Job Title: Director/Sr. Director Quality Assurance GCP	**Reports To (Title):** Vice President, Quality	**Date Created:** 16 Jan 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 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 Director/Senior Director, Quality Assurance GCP. This position will collaborate with Clinical Operations and Development, Clinical Sites, CROs, Regulatory Affairs and Quality to provide quality support and oversight to ensure clinical trials are planned, conducted, completed, and records maintained in compliance with applicable regulations, legislation, guidelines, and Soleno requirements.

RESPONSIBILITIES:

- Prepare and implement risk-based audit plans for clinical studies. Coordinate/perform and/or support GCP auditing activities and observation resolution to ensure that studies are conducted in accordance with the study protocols, regulations and GCP.
- Collaborate with Clinical Operations, clinical sites and CROs to provide ongoing quality support and oversight during the set-up, conduct and completion of clinical studies to ensure participant safety and data integrity.
- Lead the GCP inspection readiness/inspection support activities at Soleno, the CROs and clinical sites.
- Perform CQA reviews of clinical study protocols, Investigator's Brochures, Patient Information Sheets / Informed Consent and Assent forms, and other related clinical study documents as needed.
- Develop, establish, and implement GCP clinical quality assurance (CQA) oversight and management processes and procedures. Review and approve SOPs associated with Clinical Operations and Development.
- Support the Quality group's oversight efforts with quality systems such as change control, quality investigations, CAPA identification and resolution, audits, and any other recommendations to compliance issues and/or observations as they arise.
- Report and escalate significant quality observations/risks to Quality Management.
- Facilitate and/or conduct internal clinical quality training for Soleno employees and contractors.
- Participate in solving CGP compliance issues.

QUALIFICATIONS:

- BA/BS degree with a minimum of 15 years' experience in the pharmaceutical industry, including at least 10 years in a clinical (GCP) quality assurance role.
- Thorough knowledge and understanding of ICH GCP and relevant regulations, legislation, and guidances related to clinical studies and their quality oversight.
- Superior communication skills (both written and oral) are essential.

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- Demonstrated ability to communicate tactfully in a multi-disciplinary team environment with prior experience communicating with external parties including regulatory agencies (e.g. FDA).
- Working knowledge of health authority inspections and inspection readiness activities.
- Experience coordinating and conducting audits of clinical sites and CROs.
- Proven proficiency in MS Word, Excel, Power Point, and Adobe Acrobat.
- 30% travel is expected.

Salary Range: $200k - $280k (depending on level)

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