

Solenio Therapeutics Job Description

Job Title: Senior Manager, Quality Assurance GCP	Reports To (Title): Vice President, Quality	Date Created: 15 Feb 2023
Department: Quality	Job Type: <input checked="" type="checkbox"/> Full-time <input type="checkbox"/> Part-time <input type="checkbox"/> 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 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.
- Support the regulatory inspection readiness activities at Soleno, the CROs and clinical sites.
- Conduct 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 10 years' experience in the pharmaceutical industry, including at least 7 years in a clinical quality assurance role.
- Thorough knowledge and understanding of ICH GCP and relevant regulations, legislation, and guidances related to clinical studies and their quality oversight.

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- Superior communication skills (both written and oral) are essential. Demonstrated ability to contribute successfully in a multi-disciplinary team environment.
- 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: \$140k - \$190k

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