Soleno Therapeutics
Job Description

Job Title: Associate Director/Director, Quality Systems	**Reports To (Title):** Vice President, Quality	**Date Created:** 3/10/2023
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 Head of Quality Systems at the Associate Director or Director level role. This position will be responsible for developing, implementing, and maintaining an effective, GXP-based quality management system, ensuring compliance with applicable legislation, regulations, and guidelines, and conformance with applicable, current industry standards and practices.

RESPONSIBILITIES:

- Develop, implement and maintain a quality management system(s) (QMS) appropriate for the Company's size and stage of development by creating applicable policies, SOPs and records.
- Establish, manage and maintain the GXP Document Control and Training System.
- Acts as subject matter expert and provides training on Quality Management System processes (Document Management, Quality Events, Corrective and Preventive Actions (CAPA), Change Controls, Complaints), corresponding regulatory requirements and best industry practices.
- Hands-on coordination of internal Quality events, Change Controls and CAPAs.
- Manage inquiries or potential product complaints from the market, regulatory agencies, or internal/external team members.
- Investigate and or resolve internal quality events in collaboration with technical leads and vendors.
- Prepare and host periodic Quality Management Reviews to assess the health and effectiveness of the QMS.
- Develop, analyze, trend and report quality metrics.
- Implement and oversee the Internal Audit Program. Conduct Audits as needed.
- Support and administer the Supplier Management Program for Soleno's GXP programs. •

Maintain the Approved Supplier List.

- Develop the GXP audit schedule in close collaboration with the QA and functional leads. Report audit schedule compliance.
- As needed, lead, plan, and conduct GXP audits, including vendor qualification audits. •

Follow up on audit commitments with suppliers.

- Provide support in the preparation, conduct, and follow-up activities associated with regulatory inspections.

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- Provide GXP compliance guidance to cross-functional teams within the organization.
- Foster a quality culture that values innovation, continuous improvement, and personal accountability. Support GXP systems and process improvement initiatives; lead continuous process improvements.
- Other duties and responsibilities as assigned and needed.

QUALIFICATIONS:

- Bachelor's Degree in a scientific discipline.
- Minimum of ten years of experience in Quality Assurance in a biotechnology or pharmaceutical setting, including a proven history of supporting GMP, GCP and/or GVP/PVQA activities; Quality related professional certification a plus.
- Experience with QMS design and implementation.
- Strong knowledge with current regulatory guidance, including GXPs, legislation, and industry trends.
- Ability to balance multiple priorities and complex issues using logical, analytical, and efficient processes with a high level of attention to detail and quality of work.
- Excellent oral and written communication skills with strong technical writing experience is required.
- Ability to synthesize data and summarize outcomes to provide recommendations on a compliant path forward.
- Strong competency with MS Office, including template and form development, as well as Visio. •

Strong team player.

- Ability to travel.

Salary Range: $160k - $250k

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