Soleno Therapeutics
Job Description

VP, Quality

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. The VP, Quality/Head of Quality reports to Soleno's Chief Executive Officer and will be responsible for staffing, leading and developing the quality function, in line with the company stage, and ensuring global regulatory, industry, and corporate standards are met. Additionally, the role will develop and maintain a quality management system, and associated quality processes and procedures to support and oversee all GXP operations in pre-clinical, clinical and commercial programs.

RESPONSIBILITIES:

- Work closely with the Leadership Team to define and establish an integrated Quality System for all GxP (GMPs, GCPs, GLPs, GVPs) areas from R&D through Licensure and Commercialization that will be a benchmark for the industry.
- Set strategy in partnership with the Senior Leadership, and assure appropriate management oversight of Quality Performance.
- Oversee all GxP activities in alignment with business objectives and applicable regulatory requirements across all programs and functional activities.
- Lead a team of quality professionals, including objective setting, performance management, coaching, training/mentoring, development, and recruiting.
- Proactively identify issues, concerns or any potential or significant risks to the business and ensure that appropriate preventative actions are in place.
- Drive Quality Assurance decisions, approvals and guidance. Maintain a strong independent role in that regard.
- Recommend, monitor, and engage in corrective actions for all identified excursions from GxPs and SOPs, along with responsibility for coordinating all activities related to training and education in GxPs.
- Implement an Inspection Readiness program that prepares for US and global inspections by any regulatory authority and interface with regulators. Ensure the company has quality systems to ensure Inspection readiness and successful mock inspections and subsequent PAI.
- Accountable for compliant Health Authority inspections outcome and commitment to meet expected alignment.
- Lead the development, articulation, implementation and continuous improvement of the Quality Management System. Act as a champion for building a "culture of quality" across the organization.
- Foster an environment of collaboration, trust, quality, risk management, innovation and continuous improvement within Soleno Therapeutics.

QUALIFICATIONS:

- Master's Degree in a scientific discipline ore equivalent.
- Minimum of 15 years of professional quality experience in a high-performance biotechnology or pharmaceutical setting, including a proven history of supporting GMP, GCP and/or GVP/PVQA activities; ideally with a broad emphasis across corporate quality and GxP implementation. A strong GMP background in DS/DP quality is a plus. A demonstrated track record of progressively responsible leadership roles.
- Prior management of commercial quality systems including change management, risk management, supplier management, deviations/CAPA management review and product complaints.
- Broad and deep regulatory knowledge and good understanding of principles and practices of drug development and the benefits of quality compliance to corporate affairs, research and development,

clinical and commercial manufacturing, clinical trial contracting/recruiting, medical affairs, medical safety, and regulatory affairs.
- Strong knowledge with both the US and international regulations and guidance, including GXPs and industry trends.
- Experience of previously building out a global quality organization, including recruitment, objective setting, performance management, coaching, training, and development.
- Prior experience in managing health authority inspections.
- 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.
- Ability to develop new business relationships and maintain partnerships with internal and external stakeholders. Additionally, have the ability to provide cross-functional team leadership to maintain alignment and to set and meet collective operational goals.
- Excellent oral and written communication skills and can facilitate/articulate recommendations and critical decision points to senior management; demonstrated experience reducing complex subjects to key points; ability to develop a strong network across the company with strong technical writing experience are required.
- Ability to travel

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