

Soleno Therapeutics

Job Description

Senior Manager/Associate Director, Clinical and Commercial Supply Chain

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 team player and leader to join Soleno Therapeutics as Senior Manager or Associate Director, Clinical and Commercial Supply Chain. This role will be responsible for ensuring that the manufacturing throughout a product's lifecycle is executed compliantly and within agreed upon budget and timelines

RESPONSIBILITIES:

- Provide management and oversight for timely technology transfer of drug substance and drug product from early to late-stage development and from late stage development through commercialization throughout the supply chain (i.e., from regulatory starting materials, including labelling, packaging, engraving, through clinical and commercial 3PLs).
- Conceive and execute strategic sourcing plans to ensure clinical and commercial supply distribution demand requirements are met.
- Work with contract organization to establish a serialization program to ensure DSCSA compliance of commercial product.
- Provide CMC support for company's products including, but not limited to, regulatory submissions and annual product reviews.
- Collaborate with Quality to ensure compliance by contract organizations throughout the supply chain
- Other duties as assigned.

QUALIFICATIONS:

- Bachelor's degree in chemical engineering, chemistry, organic chemistry, or a related scientific discipline; graduate degree strongly preferred.
- Minimum 8 + years experience in the pharmaceutical industry including small molecules is required; experience with modified release and/or pediatric oral products a plus.
- Strong experience with establishing and managing supply chains for small molecules from development through commercialization.
- Proven track record of working with contract manufacturing organizations from development through commercialization.
- Experience establishing a serialization program appropriate for company size and supply chain complexity is required.
- Strong understanding of GMP and GDP regulations/requirements.
- Ability to communicate clearly and concisely (written/oral) with all levels of the company and with vendors.
- Must be a hands-on team player accustomed to working in a fast-paced environment.

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