

## Director, CMC

### Job Summary

Soleno's chemistry, manufacturing and controls activities will be managed by the Director, CMC, from late-stage development through commercialization. Oversight and management of Contract Manufacturing Organizations (CMOs) are critical aspects of the job. The role involves significant collaboration with other functions, including regulatory, quality, and clinical.

### Key Responsibilities

- Manage all CMC efforts to ensure development and commercialization timelines are met in the development, manufacture, testing and release of quality small molecule active pharmaceutical ingredient (API), drug product, and clinical supplies.
- Provide PIP support for manufacturing at CMOs as needed.
- Establish agenda and lead project team meetings with CMOs/CROs, including publishing of minutes and action items and ensuring follow-up of all action items until completion or resolution.
- Develop and negotiate supply agreements and review quality agreements with CMOs
- Manage process and methods validation requirements
- Author CMC sections of regulatory submissions (i.e. IMPD/INDs/BLA), and responses to regulatory agency (i.e., FDA, EMA, etc.) questions.

### Qualifications

- PhD in Chemical Engineering, Chemistry or relevant field with a minimum of 12 years of relevant industry experience, or BS/MS with a minimum of 15 years of relevant industry experience.
- Experience with solid oral dosage forms, particularly modified-release formulations from late-stage development through commercialization is essential.
- Direct experience effectively managing, API, drug product, and packaging/labeling/distribution CMOs/CROs is required.
- Direct experience preparing and reviewing CMC documentation for regulatory submissions and inspections required; contributor to key health authority meetings (i.e., EOP2, Pre-NDA) a plus.
- Strong knowledge of regulatory requirements in the US and the EU.
- Experience collaborating with a cross-functional team to develop an IVIVC a plus
- Ability to effectively manage multiple priorities through strong organization and time management skills.

**Please submit resume to Soleno Therapeutics, Inc., [hr@soleno.life](mailto:hr@soleno.life)**

Local candidates only, please.