



Aviceda Therapeutics: Associate Dir/Director Formulation/CMC

Aviceda Therapeutics is a biotech company focused on the next generation of glyco-immune therapeutics leveraging its proprietary Halos[®] technology platform to address inflammatory diseases of the innate immune system.

At Aviceda, we exploit a unique family of receptors found expressed on all innate immune cells and their associated glycobiological interactions to develop transformative medicines. Combining the power of our biology with our innovative cell-based high-throughput screening (HTS) platform and proprietary nanoparticle technology, Aviceda was able to modulate the innate immune response specifically and profoundly.

Aviceda has assembled a world-class, cross-disciplinary team of recognized scientists, clinicians, and drug developers to tackle devastating ocular & systemic degenerative, fibrotic, neurological, and immuno-inflammatory diseases.

Aviceda's offices/lab are based in Kendall Square, Cambridge, Massachusetts.

Aviceda Therapeutics is an equal opportunity employer offering competitive compensation, excellent employee benefits, and the opportunity for personal and professional growth in an outstanding and intellectually challenging environment.

Job Description:

Seeking an exceptional Nanoparticles Formulation and CMC leader to develop and implement CMC manufacturing and early-stage development technical operations strategies for both drug substance and drug product. Aviceda is seeking an individual with biopharma industry experience in CMC and technical operations, with experience in drug development, scale up, and manufacturing of nanoparticles as well as deep knowledge and understating of conjugation chemistry and biodegradable drug delivery systems. We are focused on engineering new medicines for the treatment of innate immune-inflammatory diseases for ocular and non-ocular indications.

A focus will also be placed on both local and systemic delivery strategies employing our modular therapeutic nanoparticle constructs. This is an exciting opportunity with an early-stage biotechnology platform company working on developing pre-clinical and early clinical pipeline of glyco-immune checkpoint therapeutics.

Responsibilities (including, but not limited to):

- Responsible for conceiving, formulating, and delivering nanoparticle formulations to support early discovery, preclinical, and non-GLP studies.



- Conduct experiments, independently and in collaboration with colleagues in support of project goals.
- Characterize polymers and nanoparticles using advanced analytical and characterization techniques (HPLC, NTA, nCS1, NMR, DSC, etc.).
- Develop cutting-edge conjugation chemistries to further advance Aviceda's proprietary glyco-immunology platform.
- Collaborate and integrate with chemistry/biology workflow to develop and screen nanoparticles with desired properties.
- Build relationships with and oversee Contract Manufacturing Organizations (CMOs), particularly those with nano- and micro-particle expertise, for timely execution of development needs while exceeding quality standards.
- Propose technical solutions and work with CMOs/CDMOs and academic research partners to strategize the best path forward for each lead candidate in our pipeline.
- Develop protocols for technology transfer from academic research collaborators to CMO/CDMO facilities and industry partners.
- Create strategy for all GLP, scale up and GMP manufacturing work.
- Oversee development and execution of QA/QC programs for all internal development programs.
- Set up the company strategy for the drug supply chain for all potential internal programs.
- Implement CMC SOPs and processes, while representing the company at initial CMO/CDMO audits.
- Lead and manage the timely preparation of high-quality CMC documents and submissions, including INDs/CTAs/IMPDS, NDAs/MAAs, amendments, supplements, responses to information requests, and briefing documents for regulatory agency interactions.
- Assess and communicate CMC regulatory needs to ensure all development activities comply with regulatory guidelines and regulations.
- Serve as a CMC lead in internal meetings and in meeting with business partners and regulatory agencies for all CMC related issues.

Requirements:

- Ph.D. in Pharmaceutical Sciences or Engineering, or equivalent with a minimum of two to five years of experience on CMC projects, including direct hands-on experience with nanoparticles and/or microparticles, and/or related drug delivery technologies strongly preferred. Experience with glycochemistry or glycosylation preferred. Experience with multivalent vaccines also preferred.
- Background in nanoparticle formulation development strongly desired. Specific background in polymeric nanoparticles is a strong plus.



- Hands-on experience in development of processes such as micro-fluidization, evaporation, TFF and sterile filtration.
- Varied experience in the industry, with a strong understanding of development, including Research, Technical Development, GMP Manufacturing, Quality, Supply Chain, Clinical Regulatory and Product Strategy functions.
- Excellent technical-regulatory writing and oral communication skills, with the ability to shape, frame, and present to diverse audiences. Experience in interacting with regulatory authorities required.
- Successful record of accomplishment in CMC submissions to regulatory agencies and meetings.
- Strong knowledge of current Good Manufacturing Practices (cGMPs), as well as drug development guidelines and regulations (ICH, FDA, and EMA). Ability to develop, grow and maintain strong and effective working relationships with internal stakeholders and external partners.
- Experience with program management, finance, and operations.
- Excellent communication and time management skills in a collaborative and dynamic fast-paced environment.

Job Location: Cambridge, MA

Job Type: Full-time

Education:

- M.S./Ph.D. in Pharmaceutical sciences, Materials Science, Polymer Chemistry, Chemical Engineering, Chemistry, or a related field. Minimum 2+years' experience in a biopharmaceutical industry setting.

Work authorization: work authorization in US is required

- **If you are interested in learning more about this position, please send your CV or Resume to careers@avicedarx.com**