Aviceda Therapeutics: *Principal Scientist / Associate Director (CMC – Nano Particle Formulations & Process Development)*

Aviceda Therapeutics is a biotech company focused on the next generation of glyco-immune therapeutics (GCT's) leveraging the Glyco-Code® 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 cash and stock compensation, excellent employee benefits and the opportunity for personal and professional growth in an outstanding and intellectually challenging environment.

Job Description:

Aviceda is looking for a highly skilled, motivated, and creative leader to join CMC Technical Operations & Manufacturing organization as a Principal Scientist / Associate Director. The successful candidate will also play a key role in establishing Lab Scale Nano Particle / API Formulations development, Drug Product Process Lab Scale Models, and support establishment of internal pilot plant, process scale-up, and technical transfer to external CDMOs for manufacturing of phase appropriate clinical trial material nano-particle dr through commercialization of Aviceda's nanoparticle based Glyco-Therapeutics.

Responsibilities (Technical & Operational):

Own, execute and improve the CMC Technical Operations & Manufacturing team's deliverables as follows:

- The incumbent candidate must have an ability to independently lead glycobiology formulations / Drug Product development projects with minimum supervision.
- Responsible for conducting experiments in support of developing, evaluating, and characterizing novel formulations/processes, components and supporting delivery technologies for diverse therapeutic modalities including (but not limited to), nanoparticle modality, linker / ligands and antibodies
- Provide technical representation and subject matter expertise (SME) in cross functional formulation, process and analytical investigations for nanoparticle-based modality formulation and processes.
- Design, execute, and analyze experiments for existing and novel modalities. Define the formulation, the critical parameters, and the design space.
- Support development of novel characterization techniques to characterize lipid nanoparticles to support process development and formulation design.
- Lead experiments to confirm robust process performance across the control space.
- Compile experimental and analytical results, perform data interpretation, summarize, and report on data with conclusions and recommended next steps.
- Characterize nanoparticle properties and prepare technical reports, communicate findings internally and externally, and present in cross-functional meetings.
- Collect and share relevant academic literature, leverage external consultants/SMEs, and establish new collaborations with internal groups.
- Optimize current processes to ensure robust manufacturing of Aviceda's biotherapeutic portfolio.
- Interface extensively in a matrixed environment with process and analytical development teams for process investigation support, assess new analytical technologies, support on-going process characterization and post-approval changes.
- Maintain accountability for project success and results delivery.
- Contribute to scientific and strategy discussions to advance and enhance platforms and product candidates.
- Design, develop and deliver safe, cost-effective, and robust drug product manufacturing processes, in time for GMP manufacturing of phase appropriate clinical trial material through commercial product launch.
- Encourage the use of Lean concepts, while fostering and advocating a continuous improvement mindset and culture throughout the organization, by encouraging experimentation and learning.

Qualifications:

- PhD or MS in Synthetic Carbohydrate Chemistry/Glycochemistry, Pharmaceutical Chemistry, Organic Chemistry, Analytical Chemistry, or related scientific discipline

- 10+ years of experience in Synthetic Carbohydrate Chemistry / Glycochemistry pharmaceutical, Nanoparticle Formulations Development, or biotechnology CMC/GMP environment and experience in small molecule manufacturing
- Experience in nanoparticle/ LNPs /large molecule/ADC drug product formulation development and late-stage development is a desired.
- Experience with a variety of analytical techniques including UV, Fluorescence, HPLC, LCMS, CE, GC, NMR, KF, IR, DSC.
- Effective communication skills and the ability to write detailed technical reports.
- Solid foundation in Formulation, analytical, chemistry, material science, and nano-particle characterization.
- Experience with various biophysical and light scattering techniques (DLS, NTA, Coulter Counter, etc.).
- Experience with regulatory filings and submissions.
- Experience with nanoparticle drug delivery systems.
- Good understanding of lipid and polymeric nanoparticle technologies.
- Demonstrated ability to trouble-shoot nanoparticle formulation and fabrication processes and scale-up issues.
- Experience with biophysical characterization of nanoparticles.
- Experience with high pressure homogenizer/extrusion equipment, T-mixer and microfluidic mixing systems, particle size/counting instruments.
- Experience in a cGMP setting.
- Early to Late-stage drug product process development experience is preferred.
- Demonstrates ownership and can see things through (end-to-end).
- Sound understanding of when decisions should be made / elevated.
- Conceives and drives line initiatives, technology development and CMC strategy.
- Excellent interpersonal skills and ability to work with others in a dynamic and highly collaborative environment.
- Exceptional organizational, communication, and critical thinking skills, and the ability to thrive in an interdependent and idea-rich environment.
- Strong work ethic and attention to detail.

Job Location: Cambridge, MA.

Job Type: Full-time.

Travel: As needed (~10%)

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