Senior Manager/Associate Director CMC Technical Development & Manufacturing (Hybrid)

Aviceda Therapeutics is a biotech company focused on the next generation of glyco-immune therapeutics (GIT's) leveraging the Glyco-Code® technology platform to address inflammatory/degenerative 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 **h**igh-**a**ffinity **l**igands **o**f **s**iglecs (HALOS)™ 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 Cambridge & Boston 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.

Position Summary:

Aviceda Therapeutics is seeking a Senior Manager/Associate Director of CMC Technical Development & Manufacturing to play a critical high-level role providing strategic oversight and end-to-end supervision of all CMC operational activities of the company's drug portfolio of one or more clinical and commercial development programs. This person will be responsible for ensuring that CMC project timelines stay on track. This person will serve as a key point of contact between the company and all vendors that support CMC phase appropriate external GMP manufacturing and testing activities at multiple world-wide CMOs and CROs. The successful candidate will have a demonstrated track record of technical and program leadership. This is an excellent opportunity for a highly motivated self-starter and creative problem solver who has a strong desire to make an important contribution in the development of novel glyco-biologics for autoimmune regulation. This is a high-profile position with the opportunity to innovate and be part of a dynamic team focused on driving multiple therapeutic programs for different diseases from early-stage development to final approval and launch.

Responsibilities

- Provide scientific and technical expertise in the design, qualification, and validation of manufacturing operations to meet global standards of quality and regulatory compliance.
- Lead for the development and technical transfer of the glycan therapeutic products from R&D small scale to GMP manufacturing

- Maintain effective working relationships with CMO partners as senior development expert for managing production of clinical drug substance / drug product
- Work collaboratively with Research, Quality Assurance, Regulatory, CMC Supply Operations, Clinical Operations, and Project Management. Develop goals, plans and performance metrics. Identify risk and risk mitigation strategies
- Oversee development of robust, phase propriate GMP compliant manufacturing processes meeting worldwide regulatory guidelines.
- Ensure that CMC-related applications, such as CTAs and INDs, are complete, well written, and meet all relevant agency requirements and standards
- Proactively identify CMC risks and provide recommendations on mitigation
- Represent CMC at program core team meetings providing timely updates on progress and recommendations on strategy with ability to effectively communicate subject matter specific topics to a non-CMC audience and senior leadership
- Ensure that CMC activities remain within projected timelines and budget
- Identify, review, and select the best external CROs, CDMOs and key consultants that are needed to allow smooth, efficient, and cost-effective CMC support for programs advancing to the clinic
- Lead phase appropriate analytical methods qualification, validation, and monitoring at external CROs and CDMOs including specification setting and oversite on QC labs for release DS & DP release in a timely manner.

Capabilities:

- Ability to act decisively and with urgency to solve problems
- Strong leadership and interpersonal skills to influence decision-making in a diplomatic manner
- Excellent oral and written communications with ability to present data to all levels of expert and non-expert audiences
- Accountability and self-awareness to drive positive results
- Strong Vendor Management skills
- Effective organizational and planning skills
- Flexibility to switch from strategic thinking to operational details

Education & Experience:

- MS and/or PhD in life science (biochemistry, pharmaceutical sciences, etc.) with at least 3-5 years of biopharma industry experience in product development, project management and technical operations
- Experience in working with sterile products is desired
- Proactive leadership and management skills to maintain and develop on-going glycoconjugate programs
- Experience in early and late-stage Programs is desired
- Ability to manage all interactions with CMOs, including definition of project scope, RFP submission, quote review and selection, and technical oversight

- Experience in GMP develop-ability, manufacturing and scale- up of glyco-conjugates containing products
- Design and execute the strategy for manufacturing polymers, lipids, glycan-based compounds
- Provide technical leadership and development of effective upstream and downstream processes and quality cGMP manufacturing.
- Management and technical oversight of manufacturing processes and campaigns at the CDMOs to support pre-clinical and clinical studies.
- Working knowledge of the quality concepts used in the GMP production of biotech products such as PPQ, method validation, CPPs/CQAs, IQ/OQ/PQ, raw material testing and qualification, reference standards, comparability
- Identify, assess, and mitigate quality, operational, and organizational risks; escalate key risks and issues
- Ability to work with clinical operations to deliver drug product supporting clinical studies
- Proven experience in writing and review of CMC sections of WW regulatory submissions (IND, NDA, BLA, MAA)
- Previous work experience in multidisciplinary drug development teams and broad operational experience with an in-depth understanding of drug development process. Deep knowledge of preclinical, clinical, regulatory, CMC is preferred.
- Significant experience in analytical development and validation under cGMP conditions, CMC regulatory understanding and project management is required.
- Experience with HPLC, GPC, SEC-MALS, LC/MS, NMR and FTIR and data analysis is strongly desired. Additional exposure to analytical tools used to analyze complex formulations is a strong plus.

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