

Vice President of CMC at AIRNA

Company

AIRNA, a biotech company pioneering RNA editing therapeutics to restore the health of patients with rare and common diseases, today emerged from stealth with a \$30 million initial financing led by ARCH Venture Partners. The financing enables AIRNA's experienced team to advance a pipeline of RNA editing therapeutics driven by its powerful and flexible RNA editing platform, RESTORE+.

AIRNA is seeking a VP of Chemistry, Manufacturing, and Controls (CMC) with deep experience in oligonucleotide manufacturing and experience bringing therapeutics from discovery into the clinic. AIRNA's culture is innovative, science-first, collaborative, fast-paced, and fun, and the company is looking for a distinctive leader who is excited about building great teams and a world-class company in Cambridge, MA.

Responsibilities

The Vice President of CMC will be responsible for overseeing and leading all aspects of the Chemistry, Manufacturing, and Controls processes related to the production of AIRNA's RNA editing oligonucleotide-based therapies. The ideal candidate will possess deep expertise in oligonucleotide manufacturing, process development, quality control, and regulatory compliance. The VP of CMC will:

- Lead process development and optimization activities to ensure a robust, scalable, and costeffective manufacturing process.
- Implement innovative and efficient methodologies to enhance productivity, yield, and product quality.
- Manage and optimize oligo manufacturing operations, including determining the optimal strategy for internal versus external manufacturing, and subsequently overseeing internal manufacturing facilities and/or external contract manufacturing organizations (CMOs).
- Establish and maintain robust quality control and assurance systems for oligo manufacturing processes.
- Develop CMC regulatory strategy and author quality modules for regulatory files and represent CMC in interactions with regulatory agencies.
- Work closely with the Research and Development department to develop processes to scale from research-grade oligonucleotide synthesis to GLP production, and eventual GMP production for Phase I/II clinical trials.
- Recruit, mentor, and develop a high-performing team of scientists and engineers in the CMC department. Foster a culture of continuous learning and innovation.
- Develop and implement initial process analytics and characterization, and transition to critical quality attributes and controls for clinical production, working closely with Quality.
- Develop and manage budgets for the CMC department, ensuring efficient allocation of resources to achieve project milestones and corporate objectives.



Qualifications

- Ph.D. in Chemistry, Biochemistry, Chemical Engineering, or related scientific discipline.
- Minimum of 10 years of experience in oligonucleotide manufacturing, with at least 5 years in a leadership role.
- Extensive knowledge of oligonucleotide synthesis, purification, and analytical characterization techniques.
- Proven track record of successfully bringing oligo-based products from research through development, scale-up, and clinical development.
- In-depth understanding of cGMP, ICH guidelines, and relevant regulatory requirements.
- Experience with process validation and technology transfer to clinical-scale manufacturing.
- Strong leadership, communication, and interpersonal skills with the ability to influence and collaborate effectively at all levels of the organization.

Compensation

AIRNA Bio is prepared to offer the successful candidate a competitive cash compensation package together with attractive equity participation. Additionally, a package of benefits will be provided.

Are you interested in joining the team? Please apply by emailing careers@airna.com