Associate Director, CMC

COMPANY OVERVIEW

AIRNA is a biotechnology company with a mission to transform lives, one RNA edit at a time.

AIRNA is pioneering the discovery and development of RNA editing therapeutics to realize the therapeutic potential of base editing for patients with rare and common diseases. RNA editing modality is poised to lead the next generation of RNA therapeutics by bringing the precision of gene editing technology with a potent and safe medicine that can be conveniently re-dosed and manufactured. Our RESTORE+™ platform is based on groundbreaking research by academic co-founders Thorsten Stafforst (University of Tübingen) and Jin Billy Li (Stanford University), who were the first to elucidate a therapeutic approach for precise editing of RNA.

AIRNA has received $90 million in Series A financing from world class venture capital firms, including Forbion and Arch Venture Partners, and is headquartered in Cambridge, MA with research operations in Tübingen, Germany.

JOB DESCRIPTION

The Associate Director, CMC will be a key role in our development team, providing support across all developmental and clinical programs. The successful candidate will be involved in managing a network of CMOs for Drug substance and Drug Product manufacturing for AIRNA's pipeline.

RESPONSIBILITIES

- Provide broad CMC support for internal programs from GLP tox through clinical programs
- Ensure timely Drug Substance/Drug Product supply for non-clinical and clinical studies
- Lead management of CMOs for process development and manufacturing of Drug Substances and Drug Products for toxicology and cGMP supplies
- Assist in the preparation and review of CMC sections of regulatory submissions, including IND and CTA filings
- Ensure compliance with regulatory standards including GMP, ICH, EMA and FDA guidelines
- Oversee analytical and QC activities at CMOs, including the review and approval of batch records and review of source data
- Participate and represent CMC at cross-functional meetings

QUALIFICATIONS

- M.S. or Ph.D. in Chemistry, Biochemistry, or related discipline
- Minimum of 8 years experience in process development of oligonucleotide therapeutics
- Previous experience managing CMOs for outsourced manufacturing
- Preferred experience with analytical test methods of oligonucleotides

- Strong understanding of phase appropriate analytical development and manufacturing strategies for oligonucleotides
- Experience with US and EU CMC regulatory expectations, technical transfers, and complex development & manufacturing activities
- Previous experience working in small biotech

LOCATION

AIRNA has a hybrid work model, and the role will be based in AIRNA's corporate headquarters in Cambridge, MA ~3 days per week.