Vice President, Regulatory Affairs

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:

AIRNA has an exciting new opportunity to join the team as a Vice President, Regulatory Affairs. Reporting to the CMO the VP, Regulatory Affairs will lead Regulatory Affairs for AIRNA Therapeutics and will drive the development of innovative global regulatory strategies. Responsible for the preparation and submission of high-quality sections of briefing documents, INDs, CTAs, and eventual original marketing applications (BLAs/MAAs), in close collaboration with Nonclinical, CMC, Quality, and Clinical teams, as well as external consultants and collaborators, as needed.

RESPONSIBILITIES:

- Provide global regulatory leadership to support the development of multiple, innovative RNA editing therapeutics.
- Drive the planning and implementation of meetings with regulatory authorities and effectively represent AIRNA with regulatory interactions.
- Understand and interpret complex scientific issues for assigned projects as they relate to regulatory requirements and strategy for assigned projects and provide knowledge and expertise to guide the team in appropriate regulatory strategy.
- Proactively identify regulatory issues; offer creative solutions and strategies, including risk mitigation.
- Manage and implement planning, authoring, and submission of high-quality briefing documents and clinical trial applications.
- Establish and maintain excellent relationships with regulatory agency personnel. Respond to request for additional data, organize and manage participation in meetings, and prepare

internal teams for regulatory interactions. Negotiate with regulatory authorities regarding company submissions.

- Drive adherence to global regulatory guidelines relevant for the development of; author, review, and approve, as necessary, internal documentation to ensure conformance with regulations and existing regulatory approvals.
- Collaborate with other functions to plan and execute an effective regulatory strategy in alignment with the overall development plan.
- Monitor global regulatory guidelines and publications and anticipate trends that may impact the regulatory environment to strengthen product development plan(s) and adopt regulatory strategies in a timely manner.
- Identify and implement processes, procedures, and systems appropriate for company size and stage.
- Effectively communicate the regulatory strategy, risks, mitigations and overall plans to the project teams and Executive Leadership team as required. Facilitate problem-solving and drive decision making with project teams.
- Review and approve regulatory SOPs as needed and ensure regulatory affairs function is compliant with all aspects of the QMS.
- Maintain an up-to-date knowledge of all applicable FDA/EU/other international regulations and laws and undertake training and/or information sharing with colleagues to ensure AIRNA implements appropriate processes to maintain compliance.
- Provide regulatory oversight and guidance to project teams on compliance matters, health authority requirements, clinical study design issues, logistics and operational recommendations for product development.
- Accountable for the development and implementation of global regulatory strategies throughout development of programs (e.g., regulatory meeting materials, INDs, NDA/BLAs, CTAs, MAAs, responses to regulatory inquiries, IND Safety reports, etc.)
- Manage the regulatory strategy on a continuing basis, including effectively communicating deliverables to project team and proactively drive teams and external partners to meet the designated timelines for deliverables.

QUALIFICATIONS

- Bachelor's degree in life sciences, advanced degree is preferred.
- Minimum 15 years of relevant biopharmaceutical industry experience, with at least 10 years' experience in Regulatory Affairs in leading successful NDA submissions/ approvals
- Experience interacting with regulatory health authorities and experience with submitting CTA/IND and BLA/MAA filings.
- Familiarity with Chemistry, Manufacturing, and Control (CMC), Pharmacovigilance and Quality, related matters, and their intersection with Regulatory Affairs

AiRNA

Vice President, Regulatory Affairs

- Excellent written and verbal communication skills, strong technical knowledge, including regulatory writing.
- Strong leadership qualities including strategic thinking, innovation, mentoring, collaboration, etc.
- Solid working knowledge of drug development process and regulatory requirements in the US and EU
- Detail oriented; science-based reasoning skills.
- Ability to work in a fast-paced, start-up environment.
- Independently motivated and results oriented.
- Experience providing regulatory support for early phase development is preferred.
- Excellent communicator and problem solver with the ability to influence at the Executive and Board level.
- Ability to thrive under pressure to deliver on complex projects on exacting timelines.
- Proven track record of successful regulatory submissions and approvals (FDA, EMA, etc.) for drugs
- Excellent communication, negotiation, and interpersonal skills with the ability to influence and collaborate effectively across functions and levels, both internally and externally
- Experience managing complex schedules and priorities in dynamic environments; ability to conform with shifting priorities, demands and timelines through analytical and problem-solving capabilities.