AirNexis THERAPEUTICS

Vice President, Clinical Pharmacology

About AirNexis

AirNexis is a clinical-stage biotechnology company dedicated to advancing next-generation therapies for chronic respiratory diseases. Our mission is to deliver innovative maintenance treatments for chronic obstructive pulmonary disease (COPD) that have the potential to provide improved efficacy and an enhanced patient experience compared with currently available therapies.

Through our licensed asset, focused late-stage development strategy, and global regulatory vision, AirNexis is building a meaningful presence in the respiratory therapeutics landscape. Our lead program, **AN01**, is a first-in-class dual phosphodiesterase-3 (PDE3) and phosphodiesterase-4 (PDE4) inhibitor designed to combine bronchodilatory and anti-inflammatory activity in a single maintenance therapy.

Position Summary

The Vice President, Clinical Pharmacology serves as the functional leader for clinical pharmacology and translational sciences, providing strategic direction across all phases of development from early clinical studies through regulatory approval and lifecycle management. This individual will establish and execute clinical pharmacology strategies that optimize dose selection, characterize exposure-response relationships, support regulatory interactions, and inform product labeling.

Reporting to the Chief Medical Officer, this role will partner closely with Clinical Development, Regulatory Affairs, Nonclinical Development, CMC and external collaborators to ensure successful execution of development programs.

The ideal candidate combines deep scientific expertise with broad drug development leadership and has demonstrated success leading multidisciplinary teams through late-stage clinical development and global regulatory submissions.

Key Responsibilities

- Develop and lead the overall clinical pharmacology strategy across AirNexis development programs.
- Design integrated clinical pharmacology plans supporting IND, End-of-Phase 2, Phase 3, NDA/MAA, and post-marketing commitments.
- Lead dose selection strategies utilizing PK, PD, exposure-response analyses, modeling and simulation, and quantitative pharmacology approaches.

Send your resume and cover letter to HR@airnexis.com to apply.

- Provide scientific oversight for first-in-human, SAD/MAD, food-effect, bioavailability, bioequivalence, drug-drug interaction, QT, organ impairment, population PK, and special population studies as appropriate.
- Ensure clinical pharmacology data appropriately support product labeling and regulatory submissions.
- Serve as a strategic leader across end-to-end drug development, integrating clinical pharmacology into overall development plans.
- Contribute to clinical development strategy, protocol design, statistical analysis planning, and interpretation of study results.
- Collaborate with translational medicine and nonclinical teams to bridge preclinical findings with clinical development.
- Provide clinical pharmacology expertise supporting formulation development and CMC activities.
- Lead cross-functional discussions to ensure alignment on development strategy and critical decision making.
- Serve as the clinical pharmacology representative on program governance committees.
- Author and review clinical pharmacology sections of regulatory submissions, including INDs, CTAs, briefing books, NDAs, MAAs, and responses to health authority questions.
- Lead interactions with FDA, EMA, MHRA, PMDA, and other global regulatory agencies related to clinical pharmacology.
- Ensure development strategies align with current regulatory guidance and evolving expectations.
- Represent AirNexis at scientific conferences, regulatory meetings, and partnership discussions.

Qualifications

- Ph.D. in Clinical Pharmacology, Pharmaceutical Sciences, Pharmacokinetics, Pharmaceutics, Biomedical Engineering, Pharmacology, or a related scientific discipline required.
- Additional postdoctoral training or equivalent industry experience is desirable.

Send your resume and cover letter to HR@airnexis.com to apply.

- Minimum of 15 years of progressively responsible pharmaceutical or biotechnology industry experience.
- Significant experience leading end-to-end drug development programs from early clinical development through registration.
- Demonstrated leadership across portfolio strategy and multiple therapeutic programs.
- Experience supporting global regulatory submissions and interactions with FDA and international health authorities.
- Direct experience in respiratory diseases, including COPD, asthma, idiopathic pulmonary fibrosis (IPF), or other pulmonary disorders, strongly preferred.
- Experience collaborating across biometrics, clinical development, nonclinical development, regulatory affairs, medical writing, CMC, and project management.
- Experience leading multidisciplinary, cross-functional development teams in a matrix environment.
- Experience managing external partners and consultants.
- Strong organizational and project leadership capabilities.
- Ability to thrive in a fast-paced, entrepreneurial biotechnology environment.

Preferred Qualifications

- High preference for candidates located in the San Francisco Bay Area.
- Experience supporting late-stage respiratory development programs.
- Experience with inhaled therapeutics or pulmonary drug delivery.
- Experience with global Phase 3 development and registration programs.
- Prior leadership within a clinical-stage biotechnology company.
- Experience preparing prescribing information and clinical pharmacology labeling.

Send your resume and cover letter to HR@airnexis.com to apply.