

Director, Quality Systems Management

Company Overview:

AirNexis Therapeutics is a clinical stage biotechnology company headquartered in Palo Alto, California. Guided by a seasoned leadership team, a strong investor syndicate and a clear therapeutic focus, AirNexis is working to deliver a next generation maintenance therapy for COPD that may provide improved efficacy and an enhanced patient experience compared to currently available treatments. Through its licensed asset, late-stage development focus and global strategy, AirNexis aims to establish a meaningful presence in the respiratory therapeutics landscape. The company's lead program is AN01, a dual PDE3 and PDE4 inhibitor that aims to deliver both bronchodilation and anti-inflammatory activity in a single therapy.

Position Summary

The **Director, Quality Systems Management** will provide strategic and hands-on leadership for the company's Quality Management System (QMS) and GxP document control program, supporting clinical development, outsourced manufacturing, and future commercial readiness. This role will own the development, implementation, maintenance, and continuous improvement of quality systems and serve as a key Quality partner across the organization.

The Director will oversee the full lifecycle of controlled documents and quality records, including creation, review, approval, issuance, training, revision, archival, and retrieval. The role will ensure compliance with applicable FDA, EU GMP, ICH, GCP, and other GxP requirements while fostering a strong culture of quality and inspection readiness.

Responsibilities

- Assist with the implementation, and continuous improvement of the QMS, quality policies, procedures, metrics, and processes.
- Own and manage the company's document control program and controlled-document lifecycle, including SOPs, policies, forms, templates, work instructions, and quality records.
- Establish effective document review, approval, version control, issuance, obsolescence, archival, and retention processes.
- Oversee GxP quality records, including batch, laboratory, validation, and other GMP-related records, ensuring completeness, accuracy, traceability, and retrievability.
- Administer training systems and records, including training matrices, document-driven training assignments, compliance tracking, and reporting.
- Support inspection, audit, and client readiness by ensuring timely access to accurate and complete documentation and records.
- Provide Quality oversight and guidance for deviations, investigations, CAPAs, change control, risk management, data integrity, and related quality processes.

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- Partner with Manufacturing, Technical Operations, QC, Regulatory, Clinical, and external partners, including CDMOs and contract laboratories, to ensure effective quality-system execution.
- Serve on cross-functional initiatives and provide quality leadership to support company growth and commercial readiness.
- Support supplier/GMP audits and quality oversight of external manufacturing and testing networks.
- Lead optimization of electronic document management and learning management systems and drive continuous improvement in quality-system efficiency and compliance.

Qualifications

- Bachelor's degree in Life Sciences, Chemistry, Biology, Engineering, or a related scientific discipline; advanced degree preferred.
- 10+ years of progressive Quality Assurance experience in the biotechnology or pharmaceutical industry, including significant experience with quality systems and document control.
- Demonstrated experience managing controlled documents and quality records within a regulated GMP/GxP environment.
- Experience reviewing and approving manufacturing batch records and supporting batch disposition decisions.
- Experience providing QA oversight of QC laboratories, analytical methods, and GMP documentation.
- Strong working knowledge of FDA, EU GMP, ICH, GCP, and global GxP requirements.
- Experience supporting CDMOs, contract laboratories, and outsourced manufacturing networks.
- Experience conducting or supporting supplier and GMP audits.
- Strong knowledge of deviations, investigations, CAPAs, change control, risk management, data integrity, training compliance, and inspection readiness.
- Experience with electronic document management and/or learning management systems.
- Exceptional organizational, communication, problem-solving, and cross-functional leadership skills, with meticulous attention to detail.
- Ability to balance functional area leadership with hands-on execution in a dynamic startup environment.

Base Salary Range: \$200,000 - \$225,000

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