Director, GxP Quality Assurance

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 Director of GxP Quality Assurance will be responsible for overseeing and ensuring the compliance of Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), and Good Laboratory Practice (GLP) across the organization. This role requires strategic leadership, hands-on management, and a deep understanding of regulatory requirements and quality systems in the pharmaceutical industry. The Director will lead the quality function and collaborate cross-functionally with clinical, manufacturing, regulatory, and R&D teams to ensure the highest quality standards are maintained throughout the product development lifecycle.

RESPONSIBILITIES

- GxP Compliance Leadership: Lead the implementation, maintenance, and continuous improvement of GxP quality systems to ensure compliance with applicable regulatory requirements, including GMP, GLP, and GCP, across clinical, laboratory, and manufacturing environments.
- Quality Strategy & Oversight: Develop and execute the company's GxP quality strategy, ensuring all internal and external activities comply with regulatory standards. Provide expert guidance on quality risk management, regulatory inspections, and audit preparation.
- Cross-functional Collaboration: Work closely with cross-functional teams, including Clinical Operations, Regulatory Affairs, Manufacturing, and Research & Development, to align quality standards with organizational goals and ensure seamless execution of clinical trials, manufacturing processes, and laboratory activities.

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- Audit & Inspection Management: Lead and manage internal and external audits to ensure ongoing compliance and to address any findings or corrective actions. Oversee preparation for regulatory inspections and develop robust audit responses.
- Quality System Management: Oversee the management and continuous improvement of the company's internal Quality Management System (QMS) and manage external vendor CAPAs, deviations, investigations, change controls, and non-conformance reports (NCRs).
- Training & Development: Lead the development and delivery of GxP training programs for employees to ensure a deep understanding of quality systems and regulatory requirements across the organization.
- Leadership: Foster a culture of quality, compliance, and continuous improvement throughout the organization.

QUALIFICATIONS

- Education:
    - Bachelor's degree in Life Sciences, Pharmaceutical Sciences, or related field required. Advanced degree (MS, PhD) preferred.
- Experience:
    - Minimum of 5-10 years of experience in GxP Quality Assurance, including at least 5 years in a leadership role within the pharmaceutical or biotechnology industry.
    - Demonstrated expertise in GMP, GCP, and GLP compliance and a strong understanding of global regulatory standards (FDA, EMA, ICH).
    - Experience with drug development and clinical trials, as well as a solid understanding of clinical trial operations, manufacturing processes, and laboratory testing.
- Skills & Abilities:
    - Strong leadership skills with a proven ability to manage teams, drive change, and influence across organizational levels.
    - Exceptional knowledge of GxP regulations, quality management systems, and risk management principles.
    - Excellent communication, problem-solving, and organizational skills.
    - Ability to thrive in a fast-paced, dynamic clinical-stage environment.

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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.