The Leading RNA-targeting Gene Therapy Company

Director/Sr. Director- Quality Assurance

Locana is seeking a highly motivated professional to provide oversight of all GXP QA functions. This individual will be responsible for setting up, maintaining, and continuously improving the Quality Management System, in compliance with FDA and other applicable regulations. This individual will be an integral part of the company's efforts to provide RNA-targeting gene therapy treatments for a wide range of diseases.

Responsibilities

- Plan, create and develop GXP Quality Systems to ensure compliance with relevant regulations, in a development phase-appropriate manner from preclinical to clinical development
- Participate in the submission of regulatory documents including organization, preparation, assembly, maintenance, updating and tracking of documents. Support investigational new drug applications (IND) and related correspondence with FDA
- Manage Document Control functions including SOPs and Change Control
- Participate in cross-functional teams, providing feedback and support
- Provide leadership, management and mentoring of Quality team staff
- Coordinate and/or perform Quality Management training for internal staff
- Identify, partner with, and oversee external vendors and consultants in support of the company's Quality Management needs
- Maintain up-to-date knowledge of the GXP quality field, regulations, and guidelines
- Perform other tasks as assigned

Required qualifications

- Minimum Bachelor's degree required. Advanced degree preferred. An equivalent combination of experience and education will be considered
- At least 8-10 years of relevant GXP management experience in a biotech/pharmaceutical setting, to include management of staff
- Experience with development of gene therapy products
- Experience setting up an initial Quality Management System
- In depth familiarity with FDA regulations and guidance pertaining to Quality matters
- Experience contributing to IND filings
- Experience in auditing CDMO and CRO vendors
- Experience managing a staff and contractors/consultants
- Ability to remain objective and autonomous in overseeing the Quality Program, while at the same time taking ownership and proactively working with functional departments to achieve the desired quality objectives
- Strong project management skills with ability to manage multiple projects and complete work in an accurate and complete manner according to project timelines
- Excellent interpersonal, verbal, and written communication skills
- Ability to travel to perform vendor audits as needed

Please apply directly at careers@locanabio.com.