



Senior Manager, Quality Operations

Atsena Therapeutics is a clinical-stage gene therapy company leveraging novel AAV capsids for the treatment and prevention of blindness caused by inherited retinal disease. We pride ourselves on being at the cutting edge of ocular gene therapeutics and on bringing them to the clinic with excellence, integrity, and urgency. Our lead programs, gene therapies for Leber congenital amaurosis (LCA1) and X-linked retinoschisis (XLR5), are currently being evaluated in Phase 1/2 clinical trials. We are also advancing additional preclinical programs to treat other forms of inherited retinal diseases.

Position Summary:

The Senior Manager, Quality Operations will be responsible for Quality project management of pre-clinical and clinical programs by providing GXP support to Atsena Therapeutics' Clinical, CMC, and Nonclinical teams through management of documentation review, compliance trending and maintenance of quality issues, and vendor oversight. The Senior Manager, Quality Operations will implement and maintain the Quality Management System (QMS) through quality standards, policies, and procedures, including document management in the Veeva Vault QualityDocs platform. The Senior Manager, Quality Operations will assist in GXP risk assessment activities in collaboration with business stakeholders and ensure compliance with global regulatory, vendor, and internal company quality systems requirements.

Responsibilities:

- Partners with Atsena's Clinical, CMC, and Nonclinical teams, external vendors, and investigator sites to provide GXP Quality oversight including assistance in risk assessments and quality oversight initiatives.
- Collaborates with external vendors; and Atsena Clinical, CMC, and Nonclinical teams to provide GXP and QA expertise while ensuring project objectives are met in a compliant and timely manner.
- Assesses compliance of vendors, investigator sites, study activities, etc. with study protocols, SOPs, and ICH and other applicable regulatory requirements.
- Develops and implements the internal/external GXP audit program for their clinical program(s), including scheduling, consultant oversight and audit report review and approval.
- Leads significant Quality issues management system for assigned studies, including assessment of potential root causes and remediation (corrective and preventative actions).
- Ensures appropriate and timely escalation of quality issues, including potential misconduct or issues of significant deviation, with programs/products to Leadership.
- Assists and implements initiatives that promote and maintain a quality culture and awareness towards Data Integrity and Good Documentation Practices.
- Supports GXP PAI readiness activities by partnering with internal operational and Quality leadership.

Qualifications:

- Bachelor's Degree required, preferably in life sciences.



- Minimum 5-7 years' experience working within the biotech or pharma industry, with biologics and/or gene therapy experience preferred.
- Quality assurance pharmaceutical experience, with experience in clinical research, GCP, GMP and QA compliance.
- Knowledge and understanding of pre-clinical and clinical development programs and clinical trial processes as well as quality management system.
- CQA Certification preferred.
- Experience in implementing Quality Management Systems.
- Experience with VeevaVault preferred.
- Knowledge of FDA regulations, ICH standards and other regulatory requirements.
- Ability to manage multiple projects in a dynamic and fast paced environment.

Skills:

- Accountability & Self-Management
- Communication
- Open Minded & Innovative
- Planning & Organization
- Problem Solving
- Quality
- Teamwork

Role Location: Onsite, Durham, NC

