Associate Director, QA Operations

Atsena Therapeutics is a clinical-stage gene therapy company that is leveraging novel AAV vectors designed to overcome the unique hurdles presented by retinal disease to reverse or prevent blindness. Our lead program, ATSN-201, is a gene therapy for X-linked retinoschisis (XLRS), which is currently being evaluated in a Phase 1/2 clinical trial. We are also advancing ATSN-101, a gene therapy for the treatment of *GUCY2D* Leber congenital amaurosis (LCA1) towards a Phase 3 trial. We have additional preclinical programs to treat other forms of inherited retinal disease as well as novel capsid technology suitable for addressing large indications.

At Atsena, we are bringing patients into focus. We are passionate about finding cures for visually impaired and blind individuals and are driven by cutting edge science to ensure we achieve the safest and most effective results.

Position Summary:

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

Responsibilities:

- Partner with Atsena Clinical, CMC, and non-clinical development teams, external vendors, and investigator sites to provide GXP QA oversight including development of risk assessments and quality oversight initiatives (quality plan, quality agreements, QA-QA Forums).
- Collaborate with external vendors; and Atsena Clinical, CMC, and non-clinical development teams to provide GXP and QA expertise while ensuring project objectives are met in a compliant and timely manner.
- Assess compliance of vendors, investigator sites, study activities, etc. with study protocols, SOPs, and ICH and other applicable regulatory requirements.
- Develop and implement the internal/external GXP audit program, including scheduling, consultant oversight and audit report review and approval.
- Lead the Significant Quality Issues management system for assigned studies, including assessment of potential root causes and remediation (corrective and preventative actions).
- Ensure appropriate and timely escalation of quality issues, including potential misconduct or issues of significant deviation, with programs/products to Leadership.
- Accountable for GXP document management and training initiatives via the Veeva Vault platform.
- Lead initiatives that promote and maintain a quality culture and awareness towards Data Integrity and Good Documentation Practices.

ATSENA THERAPEUTICS

- Lead GXP PAI readiness activities by partnering with internal operational and Quality leadership.
- Establish site GXP quality metrics and associated process for tracking and reporting.
- Contribute to periodic Quality Management Review and Quality Council processes.

Professional Experience and Qualifications:

- Experience with AAV Gene Therapy preferred
- Bachelor's Degree required, preferably in the life sciences
- Minimum ten (10) 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 designing, developing, and overseeing 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
- Self-motivated and ability to manage time working on multiple projects simultaneously
- Independently motivated and results oriented
- Resourceful, well organized, highly dependable, efficient and detail orientated
- Ability to work in a team environment collaboratively as well as independently with minimal supervision is essential, in both remote and onsite work environments
- Hands on, get it done approach with demonstrated cross functional capabilities
- Excellent written and verbal communication skills and strong QA technical knowledge
- Ability to interact and liaise effectively with people at all levels of the organization and with external vendors.

Role Location

- Onsite or remote