Regulatory Operations Manager

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 Regulatory Operations Manager will be responsible for overseeing the preparation, submission, and lifecycle management of regulatory filings to health authorities, including the FDA, EMA, and other international agencies. This role is crucial in ensuring timely, compliant, and high-quality regulatory submissions for our gene therapy programs across multiple jurisdictions.

Responsibilities:

- Lead the planning, compilation, publishing, and submission of electronic regulatory submissions (e.g., INDs, CTAs, BLAs, MAAs, amendments, annual reports).
- Ensure all submissions meet current regulatory requirements (e.g., eCTD specifications) and company standards.
- Collaborate with cross-functional teams including Clinical, CMC, Nonclinical and Quality to collect and organize necessary documentation.
- Maintain regulatory submission tracking systems and ensure version control and archival of regulatory documents.
- Liaise with external vendors (e.g., publishing vendors, regulatory consultants) to coordinate outsourced regulatory operations tasks.
- Monitor regulatory requirements and guidance updates from global health authorities and ensure compliance with evolving standards.
- Contribute to the development and maintenance of regulatory operations procedures, tools, and templates.
- Support health authority interactions and inspection readiness activities.

Qualifications:

- Bachelor’s degree in a life science, regulatory affairs, or a related field. Advanced degree preferred.
- Minimum 5 years of experience in regulatory operations, with a strong background in eCTD submissions in the U.S. and Europe.
- Experience supporting clinical-stage gene therapy or biologic products preferred.
- In-depth knowledge of regulatory submission requirements and publishing tools (e.g., Veeva Vault RIM).

ATSENA THERAPEUTICS

- Strong understanding of regulatory frameworks including FDA, EMA, and ICH guidelines.
- Excellent project management, organizational, and communication skills.
- Ability to work independently and manage multiple projects in a deadline-driven environment.

Skills:

- Strong verbal and written communication skills.
- Able to balance working collaboratively with a team and taking independent ownership of tasks.
- Passion for translational research, scientific innovation and creative problem solving.
- Excellent attention to detail and organizational skills, with a focus on quality.
- Able to effectively prioritize time and manage multiple projects, operating in a fast-paced startup environment.

Role Location

Onsite/Hybrid, Durham, NC