Associate Director/Director, CMC 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/Director, CMC Operations, will be primarily responsible for managing day-to-day operations at contract manufacturing and outsourced vendors and interfacing between internal PD and CDMO MSAT groups to ensure the technical foundation of activities is appropriate. This will include activities related to technology transfer, scale up and GMP manufacturing activities in support of the Atsena portfolio of early, late and eventually commercial AAV products and related precursor materials. The scope includes providing technical and strategic input for CMO plans, review and approval of executed GMP documents and general performance management

Responsibilities:

- Manage and engage with CDMOs, virtually and as Person-in-Plant during manufacturing activities to ensure Drug Substance and Drug Product are completed in accordance with cGMP requirements and established process requirements
- Collaborate with internal PD/AD groups to prepare for and execute technology transfers to CDMOs
- Provide technical expertise and leadership in technology transfer planning, and execution for GMP readiness in collaboration with CMDO partners and support assessments of process deviations and CAPAs at CDMOs for acceptability
- Oversee the preparation of technical documents supporting process definitions, specification development and transfer plans including batch records and technical reports
- Collaborate with internal functional groups (PD/AD, Quality, Program Management and clinical teams) to ensure delivery in accordance with established program timelines for both internal and external delivery
- Collaborate with internal and external groups to design and implement process improvement and optimization strategies
- Identify manufacturing problems and initiate/coordinate manufacturing investigations with external MSAT teams and Quality Assurance

- Support the establishment of a formal supply chain function in support of global distribution of Atsena's products for clinical and commercial use.
- Develop, review and finalize technical documentation and reports to ensure scientific validity and to meet regulatory requirements including authoring Module 3 sections of IND/CTA and BLA submissions
- As needed, provide technical due diligence support for evaluation of new contract service providers in support of Atsena's qualified vendor network

Qualifications:

Minimum of B.Sc. degree in in biological sciences such as biochemistry, immunology, or cell and molecular biology with a minimum of 8-10 years' experience in the biotechnology or pharma industry. At least 5 years' experience successfully building, leading and managing a team of scientists and engineers in a CMC environment. Demonstrated experience in process development and/or manufacturing in biologics and/or gene therapy environment is essential, with process validation experience highly preferred. Strong communication, management and interpersonal skills to influence effectively across the organization and with contract partners. Some travel is required.

Skills:

- Expertise in process development and/or manufacturing biologics or gene therapy products in a GMP environment
- Strong verbal and written communication skills.
- Able to balance working collaboratively with a team and taking independent ownership of tasks.
- Passion for scientific innovation and creative problem solving.
- Excellent attention to detail and organizational skills, with a focus on quality and technical excellence.
- Able to effectively prioritize time and manage multiple projects, operating in a fast-paced and dynamic environment.
- Experience in late-stage development or commercial manufacturing of gene therapies will be highly valued
- Experience in process transfer in support of global clinical trials will be highly valued

Role Location

Onsite

ATSENA THERAPEUTICS