75 State Street, Suite 1400, Boston MA 02109 USA

Position Title:	Senior Director, Head of Drug Substance
Department:	Pharm Sci Tech Ops
Hiring Manager:	SVP, Pharmaceutical Science & Tech Ops

We are a team of experts from multiple disciplines who have come together driven to bring hope and life-changing therapies to patients and their families.

Position Overview:

Astria Therapeutics is dedicated to bringing hope with life-changing therapies to patients and families affected by allergic and immunological diseases. Astria's pipeline includes our lead program, STAR-0215, a monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema, as well as STAR-0310, an OX40 monoclonal antibody antagonist currently in pre-clinical development for atopic dermatitis (AD) and being explored for other allergic and immunological diseases.

We are seeking an experienced leader to join Astria as the Senior/Executive Director, Head of Drug Substance. This role will oversee all drug substance process development for the company. This position will play a key role in driving the portfolio forward from early process development through late stage include process characterization and validation and commercialization. The Head of Drug Substance will have a pivotal role in providing strategy, shaping future organizational design, and innovation for the PharmSci organization. This senior leadership position requires a strategic thinker with a deep understanding of development including late stage and commercialization, exceptional relationship building and technical skills, and the ability to collaborate cross-functionally to ensure efficient and effective development throughout our programs at Astria. This role will also oversee all aspects of drug substance process and technology development and be a key partner for the other PharmSci functional heads. This leader will initially manage a small team of vendors and internal reports with an opportunity for future growth and reports to the SVP of Pharmaceutical Sciences and Technical Operations.

Responsibilities:

- Lead drug substance team through preclinical and clinical development to commercialization across Astria's pipeline. The role will have end to end responsibility of drug substance process development and technical support.
- Drive, build, and enhance strategic relationships with CDMO and other partners to advance Astria's patient-guided drug development pipeline.
- Provide strategic and operational oversight, content creation of all regulatory documents and request for information.
- Partner cross functionally broadly throughout the organization including program teams, research, clinical development, medical affairs, new product planning, regulatory affairs, and corporate communications.

- Represent PharmSci holistically internally and externally as needed. Activities include due diligence, regulatory interactions, indication expansion, technology and innovation opportunities, project team and portfolio review committee.
- Develop, own, and execute against the operational budget pertaining to drug substance including manufacturing and process development.
- Provide mentorship and guidance to colleagues within the organization as well as outside of PharmSci.

Qualifications:

- Ph.D. in biochemical engineering, chemical engineering, biochemistry, or appropriate technical discipline with 12-15 years industrial bioprocess development/scale-up and manufacturing experience. The ideal candidate would have extensive experience in cell line and upstream process development. BS/MS with minimum of 15-20 years relevant industrial experience
- 5 years' direct management experience is required.
- Strong leadership skills with experience defining the vision for the patient affairs function including strategic planning and supporting the development and growth of team members.
- Proven track record of building trusting, meaningful relationships with key stakeholders, cross functional organizations and CMDO vendors and partners
- Strong understanding of the legal, regulatory, and compliance environment, including a strong understanding of guidelines and best practices for drug substance development
- Highly collaborative, able to successfully develop and maintain strong working relationships cross-functionally with colleagues and with external stakeholders.
- Excellent communication and presentation skills
- Travel: 25% (domestic and international)