



Position Title: Director, Drug Substance
Department: Pharmaceutical Sciences & Technical Operations
Hiring Manager: VP, PSTO

Our vision is a world where science, passion, and compassion create better todays and more tomorrows.

Company Overview:

Astria Therapeutics (Nasdaq listing, ATXS) was formed following the acquisition of Quellis Biosciences, Inc., by Catabasis Pharmaceuticals in January 2021. Astria is focused on developing its lead program STAR-0215, a potent and long-acting monoclonal antibody plasma kallikrein inhibitor, as the potential best-in-class and most patient-friendly prophylactic treatment option for the prevention of attacks in patient affected by hereditary angioedema. Astria will also seek to develop a pipeline in the areas of allergy and immunology with a focus on rare and niche indications through internal discovery efforts and in-licensing.

Concurrent with the acquisition of Quellis, the Company entered into definitive agreements for a private placement with institutional accredited investors to raise approximately \$110 million. The financing was led by Perceptive Advisors, with participation from Fairmount Funds Management LLC, RACapital Management, Cormorant Asset Management, Venrock Healthcare Capital Partners, Logos Capital, BoxerCapital, Acorn Bioventures, Commodore Capital, Surveyor Capital, Acuta Capital Partners, Sphera Healthcare, and Serrado Capital LLC. As of June 20, 2021, the Company had cash, cash equivalents, and short-term investments of approximately \$140 million. The Company expects that it has sufficient cash to fund its current operating plan through 2023.

Astria is well-poised to continue successfully advancing their current programs — with the STAR-0215 program on track to potentially demonstrate clinical proof of concept of its differentiated profile and long antibody half-life in Phase 1a next year — in addition to growing and developing additional product candidates and partnerships.

STAR-0215:

Astria’s lead program, STAR-0215 is currently in preclinical development for the treatment of HAE, a rare genetic disorder characterized by severe, recurrent, unpredictable, painful, and sometimes life-threatening swelling in the face, limbs, abdomen, and airway. Astria is developing STAR-0215 to be a long-acting monoclonal antibody inhibitor of plasma kallikrein, dosed once every 3 months or longer, with the goal of providing the most patient-friendly chronic treatment option for people living with HAE. The company expects to file an Investigational New Drug (IND) application for STAR-0215 in mid-2022 and plans to initiate a Phase 1 clinical trial with initial results anticipated by year end 2022.

Position Overview:

Astria Therapeutics is seeking a driven, thoughtful leader in the Drug Substance area of expertise. The successful candidate will provide strategic leadership for the operational aspects of the clinical drug substance manufacturing so that a full continuum of services exists to respond to the organizational development needs.

Responsibilities:

- Proven experience in late and early stage biologics manufacturing and process validations.
- Experience in management of out-sourced manufacturing/development activities.
- Proven tech transfer and scale-up experience, from development lab to cGMP manufacturing.
- Demonstrated ability to function in a collaborative/team-oriented CMC environment.
- Experience in authoring IND/BLA/MAA and responding to health authority information requests.
- Ability to influence others without direct authority.
- Ability to communicate and connect with all levels of the organization
- Strong project leadership and resource management skills.
- Contract management experience
- Strong background in cGMP, cGLP, and ICH requirements.
- Demonstrated skills in project management and handling multiple projects simultaneously.
- Good verbal and written communication skills.
- Direct all activities of the CMO-based clinical manufacturing of large molecules including but not limited to monoclonal antibodies, fusion proteins, bi-specifics, antibody-drug conjugates and other biologics from early to late stage tech-transfer and clinical manufacturing.
- Oversee and manage process validation studies of molecules
- Manage outsourced manufacturing activities at CMOs. • Lead and manage external collaborations, ensuring close partnership through scientific and strategic understanding, and attention to partner priorities, to maximize integration and synergy between BMS and partner.
- Identify, contract and transfer technology to CMOs appropriate for scale-up and GMP implementation for clinical manufacturing.
- Exercise independent judgment to apply strategy for biologics clinical manufacturing and implementation to enable successful regulatory filings.
- Ensure suitable quality, optimal economics, and adequate supply chain security for biologics clinical products.
- Participate in Project and CMC development teams, in leadership and/or member roles, as required.
- Prepare, forecast and manage budgets for drug substance manufacturing projects with precision, transparency and flexibility
- Assembles and submits relevant manufacturing facility and process information to the Regulatory Affairs CMC function for the development of CMC section of NDA.
- Participates on due diligence teams and provide evaluations as required.
- Identify strategic and operational issues, develop proposals, outline solutions, and negotiate time commitments and resources.

Qualifications:

100 High Street, 28th Floor, Boston, MA, 02110

- Ph.D. in biochemical engineering, chemical engineering, biochemistry, or appropriate technical discipline with 10+ years industrial bioprocess development/scale-up and manufacturing experience, including mammalian cell culture and associated downstream unit operations.
- MS with minimum of 15 years relevant industrial experience or BS with minimum of 20 years relevant industrial experience may be considered.
- Minimum of 8 years direct management experience is required.