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

Position Title:	Senior Scientist / Assoc Director Analytical Development
Department:	Pharmaceutical Sciences & Technical Operations (PSTO)
Hiring Manager:	Senior Director Analytical Development, PSTO

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

Company Overview:

With patients as our guiding stars, Astria Therapeutics' dedicated and passionate team is devoted to bringing life-changing therapies to patients and families impacted by hereditary angioedema (HAE) and rare and niche allergic and immunological diseases. Our company was formed following the acquisition of Quellis Biosciences, Inc., by Catabasis Pharmaceuticals in January 2021, becoming what is now Astria Therapeutics (Nasdaq: ATXS). Our name comes from the Greek word for star, and at Astria, patients are the stars that guide our journey. Their stories inspire us, their successes energize us, and their challenges give us purpose. Our lead program STAR-0215, is a monoclonal antibody inhibitor of plasma kallikrein designed to provide long-active, effective attack prevention for HAE. We also plan 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. We are well-positioned to continue successfully advancing our current programs — with STAR-0215 on track to potentially demonstrate clinical proof of concept of its differentiated profile and long antibody halflife 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 curious and experienced analytical Snr Scientist/Associate Director to support the development of biologics at our drug substance and drug product manufacturers. The successful candidate will provide scientific expertise to oversee the development of critical quality and compendial assays, in addition to future proofing product development longer term through proactive assessments of product attributes. You will join an exciting and experienced pharmaceutical sciences

and technical operations (PSTO) team who are committed to developing new medicines for rare and niche immunologic and allergic diseases.

Responsibilities:

- Supports the external development of critical quality and compendial assays to enable manufacturing and release of early phase biologics at external CRO and CTOs
- Identifies new analytical test method laboratories and evaluates laboratory capabilities to support Astria's new product discovery
- Leads the selection of potency assays- designs and oversees potency assay comparability assessments at external vendors in compliance with FDA and EMA guidelines
- Ensures analytical assessments performed at external CTOs are conducted in a timely fashion and in compliance with phase appropriate GMP regulatory guidelines
- Works with the Senior Director of Analytical development using design of experiments (DOEs) approaches to support assay development, qualification and validation and oversees assessment of in-process control methods to support biologics development
- Guides the external establishment of Standard Operating Procedures for laboratory test procedures and ensures SOPs comply with organizational and regulatory requirements.
- Facilitates tech transfer from Astria research teams of analytical assays to support non-clinical and clinical stage development; ELISAs, UV, FLR, HPLC and LC-MS/MS
- Identifies gaps in assay development and validation activities, critical reagents and reference standards programs
- Contributes to PSTO investigations related to atypical process or assay performance, identifies critical issues for optimization and ensures timely completion of activities
- Collaborates with cross-functional team members within PSTO and across Astria (Quality, Regulatory, Research, Clinical and Non-Clinical) to evaluate product quality attributes and maintain product consistency
- Maintains knowledge of current ICH and FDA assay guidelines, and provides method transfer support, advocates of use of new methodologies and evaluates current methods
- Supports assembling information for regulatory submissions, stores data in Benchling / electronic laboratory notebooks as needed
- Participates in product specific program team meetings, presents data, and escalates issues to management in a timely manner
- Contributes to statistical evaluation of stability data related to establish shelf-life and predict liabilities
- Participates on due diligence teams and provides analytical evaluations as required.

Qualifications & Experience:

- Ph.D. in biochemistry, chemistry, biology or similar discipline with 3+ years industry experience in developing, qualifying and or validating analytical methods to support GMP drug development
- MS with minimum of 8 years relevant industrial experience or BS with minimum of 10 years relevant industrial experience may be considered.
- Experienced in tech transfer of analytical assays, mapping out milestones for assay qualification and participating in program development activities
- Experienced in applying and managing implementation of some of the following assays: ELISAs, Cell-based potency, SEC HPLC, ICIEF, SDS/CE, DLS, SEC-MALS, CEX, UV, FLR, CD, LC-MS

- Experienced with statistical analysis of analytical data following ICH guidelines, e.g. LOQ, LOD, precision, accuracy, stability, degradation, and data reporting using SAS, SPSS, JMP or other statistical software

Preferred Skills

- High level of curiosity and interest in application of technical solutions to solve problems
- Clear communicator with an interest in joining a dynamic team
- Data driven with a strong interest in analytical methods