



Position Title:	Vice President, Early Clinical Development
Department:	Clinical Development
Hiring Manager:	CMO

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.

Astria is seeking a creative, integrative thinker who is driven to use cutting edge approaches to advance early development, particularly clinical pharmacology and translational medicine. Reporting into the CMO, this individual will provide scientific leadership to develop and execute impactful clinical pharmacology, pharmacometrics (PMx) and translational medicine strategies in support of key decisions for programs in Astria's portfolio. This role requires diverse PK, PD, and PMx experience in drug development within pharma/biotech, agility in being able to handle both hands-on efforts and strategic leadership for a dynamic portfolio, and a strong track record of scientific and collaborative leadership.

Responsibilities:

- Drive clinical pharmacology strategy for our pipeline, including design and implementation of program specific clinical pharmacology studies, data analysis, internal decision points, and external regulatory interactions.
- Work collaboratively with translational sciences and drug discovery to lead the development and implementation of clinical pharmacokinetic, pharmacodynamic, and PMx tools as well as strategies and execution plans to inform clinical and regulatory decisions through all phases of drug development, particularly in defining early proof of concept (EPOC) and proof of concept (POC) strategies in humans.
- Be a critical driver and influencer in key company decisions including development candidate selection, patient dosage selection, clinical strategy, and regulatory filing strategy.
- Drive contributions that focus on generation of information that support safe use, targeting of the right patients and profiling to allow optimal positioning for clinical and commercial success.
- Manage and be accountable for clinical pharmacokinetic, pharmacodynamic, drug interactions, and anti-drug antibody results analysis for all clinical trials in all jurisdictions.
- Leverage internal and external expertise and your own network to draft, plan, implement, and execute against organizational objectives.
- Actively partner with Clinical Development, Clinical Operations, Regulatory Affairs, Nonclinical Development, Pharmaceutical Sciences, Discovery and Translational Sciences and other functions in driving asset and company strategy to fruition.
- Be external facing: drive creative and operational relationships with external leaders and vendors to optimize Astria's early development strategy and operational effectiveness.



- Partner in leading and optimize the Drug Discovery Research Development Interface to support transition of programs from research to development.
- Participate as a core member of Astria's senior leadership team

Qualifications:

- MD, PhD and/or equivalent and experience in one or preferably more of early clinical development, translational medicine, clinical pharmacology, pharmacometrics, and pharmaceuticals disciplines with at least 15 years of total relevant experience (biologics experience is preferred)
- Experience in at least two previous new drug applications and demonstration of a working understanding of clinical pharmacology-related regulations for biologics
- Experience drafting and executing Phase 1 and initial patient (EPOC/ POC) trials
- Experience leading and applying PMx approaches such as population PK, PK/PD, and disease progression models to support research and development.
- Excellent quantitative skills and a vision to leverage the science of dosage projection/simulation, quantitative systems pharmacology, mechanistic toxicology risk assessment, and pharmaceuticals in a cutting-edge discipline.
- Outstanding interpersonal and communication skills both written and oral and ability to communicate complex information succinctly.
- Excellent analytical and problem-solving skills and ability to manage multiple projects and initiatives simultaneously in a fast-paced environment.
- Effective skills directed toward driving collaboration, achieving results, influencing, and resolving conflicts across internal and external project teams.