

75 State Street, Suite 1400, Boston MA 02109 USA



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

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

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 preclinical development for atopic dermatitis (AD) and being explored for other allergic and immunological diseases.

Astria is seeking a creative leader who is driven by patients and science to advance our pipeline. The Vice President, Late Clinical Development will be responsible for leading clinical development, providing scientific/clinical and product development leadership and supporting development of programs across the Astria portfolio. The ideal candidate will have deep expertise in early to late-stage clinical development and a demonstrated track record of advancing medicines through market authorizations with strong scientific rigor and a thorough understanding of target and disease biology.

Responsibilities:

- Responsible for mid, late, and life-cycle (including post-marketing commitments) clinical development strategy, plans and implementation.
- Partners with translational medicine and early clinical development on first-in-human and other Ph 1 trials
- Partners with medical affairs on strategy and operations to expand value paradigms for Astria's programs
- Partners with new product planning and program team leadership to develop asset strategies and target product profiles.
- Works closely with patient advocacy internally and externally to fine tune product profiles, development strategies and plans, and impact where needed and possible care paradigms
- Represent Astria externally where needed regarding clinical development activities
- Works in close partnership with clinical operations and other functions within and beyond the program team to design optimal trial designs and ensure operational effectiveness of the trials
- Effectively manages resources to ensure successful development and implementation of development strategies across programs and facilitating effective, efficient decision making related to protocols, development programs meet timelines, budget, and objectives.
- Leads clinical strategy, including benefit-risk assessments, for all regulatory submissions and interactions
- Ensures readiness and competence of staff for clinical program needs, including compliance with Good Clinical Practices and Astria SOP's.
- Manage operating budget for department.

- Jointly accountable, along with cross-functional colleagues, for the delivery of projects on time and on budget.
- Develop, lead, and inspire a team of physicians and clinical scientists; inspire Astrians for full support of our clinical initiatives
- Provide specific therapeutic area expertise to enhance innovation and efficiency in clinical trial design and execution.
- Provide key contribution to IND, NDA, PMA submissions via overseeing medical documentation and active participation in meetings with regulatory agencies.
- Establish and develop relationships with investigators, KOL's, in close collaboration with the Medical Affairs department.
- You will be an essential member of the senior leadership team.
- Finally, you will provide medical, disease-specific, and development perspective into specific research programs or broader research initiatives.

Qualifications:

- MD, MD/PhD, or equivalent
- Broad understanding of the evolving clinical and global commercial landscape preferably in allergy and immunology
- Must demonstrate strong learning agility and perseverance.
- 10+ years of experience in the biopharmaceutical clinical and/or medical function, with 5+ years of clinical development experience
- Expertise in innovative clinical study design, analysis of clinical data and publications and working knowledge of biostatistics and pharmacokinetics/pharmacodynamics
- Understands the drug development process from pre-IND through BLA
- 5+ years of experience in clinical R&D as investigator and/ or within the pharmaceutical/ biotech industry
- Experience interacting with health authorities in the US and EU; Japan and other Asia experience is desired
- In-depth knowledge of ICH-GCP and other application regulatory guidelines
- Highly organized, outcome-oriented, self-motivated performer; demonstrates grit and determination
- Excellent interpersonal skills, ability to develop important relationships with key stakeholders across a variety of disciplines, good conflict management and negotiation skills
- Ability to forge and nurture key partnerships and collaborations with the external scientific community
- Ability to travel domestically and internationally (~10%)

Astria's Commitment:

At Astria, we are committed to building a diverse team where every Astrian is empowered to bring their authentic self to work. We embrace a patient-first, people-always culture in which all Astrians and our collaborators have a sense of belonging and receive the support they need to thrive. We invest in our people through our words, our actions, and our values. We are working to develop and implement initiatives that promote diversity, equity, and inclusion throughout the organization and foster a culture of openness, respect, and collaboration, where all voices are heard, and everyone is valued for their unique perspectives and contribution.

People are our greatest asset, and only with a diverse team can Astria shine brighter. Together we can bring our passion and compassion to the work of delivering life-changing therapies to patients, families and communities.