## 75 State Street, Suite 1400, Boston MA 02109 USA

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| **Position Title:** | Vice President, 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 is seeking a creative leader who is driven by patients and science to advance our pipeline. The Vice President, Clinical Development will be responsible for leading clinical development after proof-of-concept, 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 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 and implementation
* Partners with translational medicine and early 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
* 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.
* Responsible for the generation and continual refinement of the clinical development plans (all regions) for Astria’s portfolio from IND to POC to NDA.
* 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.
* Partners with new product planning and the full commercial team to ensure the product profile is tuned to patient’s expectations while meeting the needs of the market within regulatory frameworks
* 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 rare disease
* Must demonstrate strong learning agility
* 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 (~20%)