75 State Street, Suite 1400, Boston MA 02109 USA

Position Title:	Vice President, Head of Safety and Pharmacovigilance
Department:	Safety
Hiring Manager:	Chief Medical Officer

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.

Position Overview:

Astria is seeking an innovative and collaborative individual who will play a pivotal role in fostering a culture of safety within the company ensuring that Astria remains at the forefront of patient safety and pharmacovigilance. The individual will be responsible for the strategic implementation, execution, and management of pharmacovigilance and risk management activities in alignment with Astria's development products. Reporting into the CMO, this individual will emphasize the importance of a safety-centric approach and must effectively collaborate cross-functionally at all levels in the organization as well as with external safety service providers and regulatory authorities.

The VP, Head of Safety and Pharmacovigilance will lead and is accountable for the safety datasets for Astria's programs by providing strategic medical oversight for all pharmacovigilance functions which includes but is not limited to: participating in regulatory authority interactions, including preparatory activities (background/ dossier documents), overseeing, leading and mentoring the PV team and external vendors/safety service providers; DSUR updates, product benefit- risk management; oversight of PV Operations, Quality and Compliance for investigational products; address any inquiries related to product safety; and ensure proactive safety signaling and timely risk-benefit assessments of safety data. The candidate will play a visible role in providing safety leadership and advisement in companywide forums and initiatives.

Responsibilities:

- Build a culture of safety within Astria by establishing and maintaining a safety and PV infrastructure that highlights "safety by design" in our development activities with the goal to ensure the protection of clinical trial participants and patients.
- Participation in Astria's safety review committee, clinical trial-specific safety review committees, and, where applicable, data monitoring committees.
- Lead, oversee and direct all aspects of pharmacovigilance and risk management activities for Astria products in development
- Design, direct, and conduct ongoing safety surveillance of Astria's drug products using internal and external resources to ensure delivery of high-quality Pharmacovigilance services
- Negotiate contracts, interact with, and supervise the activities of CROs/safety service providers and consultants for Pharmacovigilance services
- Inform the Chief Medical Officer and Executive Leadership Team members on the changing risk-benefit profile of company products and competitors' products in clinical trials, based on analyses/evaluation of potential safety signals and implements appropriate safety updates and risk mitigation plans
- Provide strategic planning, implementation, and management of drug safety activities to support clinical development of company products and actively contribute to corporate risk management related to safety

- Provide oversight of all clinical safety activities including review of medical coding of AEs, concomitant medications, and processing of SAEs through the entire lifecycle including preparation of analyses of similar events (AOSE) for unexpected and related serious adverse events (SUSARs) from clinical trials
- Lead responses and resolutions to safety questions from Regulatory Authorities, as well as Regulatory Agency audits and inspections, and corrective action plans.
- Lead signal management activities and participate in safety governance bodies
- Direct the development, preparation, and review of; periodic and annual safety reports (e.g., DSUR), investigator communications, and other reports as necessary that relate to product drug safety
- Provide medical expert safety review input into all critical documents for clinical development plans of products (e.g., Protocols and Amendments, Clinical Study Reports, Informed Consent Documents, Investigator Brochures (IB), Investigational Medicinal Product Dossier (IMPD), Safety Review Committees, etc.)
- Manage PV budgets
- Manage and oversee all PV resources including internal employees and external contractors
- Monitor industry best practices and changes in global safety regulations and guidelines
- Recommend changes and upgrades to existing departmental policies, SOPs, and systems to ensure global regulatory compliance
- Provide strategic insight to the Company on safety-related questions from external sources etc.
- Coordinate effectively across functions including Clinical, Medical Affairs, Regulatory Affairs and Quality effectively to perform the above responsibilities
- Mentor the team towards continuous improvement/enhancement of PV work procedures consistent with good pharmacovigilance practices for regulatory inspection readiness
- 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.
- Participate as a core member of Astria's senior leadership team.
- As the pipeline grows and progresses, lead and build a team to support execution of responsibilities described here

Qualifications:

- M.D., D.O., M.B.B.S. is required.
- Minimum of 10 years of global experience in Drug Safety in a biotechnology required
- Deep understanding of risks and risk mitigation steps related to safety signals and pharmacovigilance
- Expert knowledge of FDA safety regulations, ICH Guidelines, EU GVP and other applicable regulatory guidance documents; expertise in global safety regulations
- Knowledge of U.S. and International Regulatory Reporting Requirements and of the clinical development process.
- Expert knowledge of relational database applications (including ARGUS, ARISg, or other safety database).
- Expertise in safety assessments, safety signal detection and risk management, including interactions with Regulatory Authorities
- Demonstrated ability to solve problems with innovative solutions along with strong organizational skills
- Possess strong and dynamic leadership skills, with excellent written, verbal, and presentation skills
- Effective team player who fosters collaboration within and across functional areas
- An accurate understanding and precise focus on the risk management aspects of the safety

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.