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

Position Title:	Director/Senior Director, Global Regulatory
Department:	Regulatory
Hiring Manager:	VP, Head of Regulatory

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

Director/Senior Director, Global Regulatory Affairs:
Astria Therapeutics is seeking a highly motivated Director or Senior Director with industry experience in leading global regulatory submissions both internally and externally. The successful candidate will be a savvy and enthusiastic leader who ideally has some experience with all aspects of the Regulatory Affairs function, including writing key regulatory documents, submission preparation, electronic publication, project management, oversight of key regulatory activity execution by cross-functional teams and external vendors, due diligence activities, Regulatory CMC, and high-level strategy.

This role will report to the VP, Head of Regulatory Affairs.

Responsibilities:

- Lead cross functional teams in preparing successful global regulatory submissions (NDA/BLA/IND/CTA), health authority interactions, label discussions, and securing approvals, write key documents, oversee the efforts of and liaise with external regulatory operations and electronic publication vendors.
- Proactively drive program teams, establish appropriate level of urgency, and maintain focus on deliverables. Lead team to identify and recommend solutions to problems and pathways to overcome barriers for strategy development and execution.
- Drive decision making processes and escalate issues, as needed, ensuring proactive planning is taking place to enable delivery of all regulatory milestones across the program. Identify and resolve potential systemic bottlenecks and constraints. Prepare and deliver reports and metrics on major regulatory milestone status, potential critical issues, constraints, bottlenecks, regulatory risk, mitigation management (and proposed solutions to support decision-making) across individual programs.
- Develop, drive, and implement regional or global regulatory strategy ensuring that is crafted to deliver rapid approval with competitive labeling that is identified by the business, markets and patients and participate in target product labeling creation.
- Drive the strategy for and creation of briefing documents and lead the team through meeting rehearsals and moderate the meeting itself. Own negotiations with health authorities.
- Lead a Global Regulatory Strategy Team (GRST) comprising regulatory affairs and key contributing cross-functional members.
- Deliver on regulatory milestones, including an assessment of risks and mitigations, emerging data, and the probability of success.

- Plan and construct global dossiers and core prescribing information, including product maintenance, supply, and compliance activities.
- Review corporate and product-related materials for Astria's stakeholders to ensure compliance with regulatory laws and regulations.
- Participate in diligence reviews and analyses of key external vendors and potential business development opportunities.

Required background and experience:

- 15+ years of experience in the pharmaceutical industry.
- Advanced degree preferred.
- Experience with Regulatory CMC a plus.
- Regulatory Information System experience a plus.
- Experience developing phase appropriate regulatory SOPs.
- Comprehensive experience and expertise in regulatory operations and submissions.
- Strong leadership skills, experience, and strategic thinking with a proven track record of building collaborative relationships to meet corporate goals.
- Enthusiastic team player.
- Experience supporting both early and late phase development, including development and filing of associated regulatory submissions.
- Experience in a start-up environment with a balance of risk taking and advancing products efficiently.
- Experience managing and collaborating with outside partners/vendors.
- Strong experience in managing external collaborations and CRO activities.
- Ability to review, understand and explain the regulations and guidance documents to guide project teams.
- Proven success in communicating to and negotiating with FDA and global health authorities and managing clinical trial applications in several geographies around the world (for example US, Europe, Latin America, Asia).
- Excellent communication and project leadership skills and ability to work effectively in a team setting.
- Strong understanding of the drug development process, CTD/eCTD structure and requirements for US FDA submissions and knowledge of global regulatory submission requirements.
- Ability to accommodate to fast changing priorities and meeting established deadlines.
- Excellent communication and project leadership skills and ability to work effectively in a team setting.