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| **Position Title:** | Sr. Manager/Assoc. Director, Global Regulatory Affairs |
| **Department:** | Regulatory |
| **Hiring Manager:** | VP, Head of Regulatory |

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

**Senior Manager/Associate Director, Global Regulatory Affairs:**

Astria Therapeutics is seeking a highly motivated Senior Manager or Associate Director with industry experience in leading global regulatory submissions both internally and externally. The successful candidate will be a self-motivated individual who has experience with global regulatory submissions preparation and vendor oversight, regulatory intelligence, regulatory document management, and regulatory writing key regulatory documents, electronic publication, project management, and interactions on cross-functional teams.

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

**Responsibilities:**

* The Sr. Manager/ Associate Director of Regulatory Affairs will work closely with cross functional development team members and will assist in developing and communicating the Regulatory strategy and submission timelines as well as provide operational advice to the cross-functional development team including the CMC, Nonclinical, and Clinical functions. This advice includes, but is not limited to, decisions regarding health authority interactions, regulatory submissions, and other regulatory requirements in line with corporate objectives and timelines.
* Project manage, plan, coordinate, prepare, review, and oversee all aspects of document and submission preparation for FDA and liaise with any external ex-US health authorities in support of INDs, IMPDs, CTAs, amendments, safety reports, and annual updates for assigned projects. Project manage and liaise with external electronic publishing vendors.
* Interpret and communicate Regulatory expectations to stakeholders to execute program objectives in compliance with applicable regulations.
* Contribute to the development of policies, procedures (RA SOPs), and best practices commensurate with the requirements of a rapidly growing company.
* Acquire Regulatory Intelligence, liaise with Regulatory Intelligence vendors, and disseminate the information to key stakeholders.
* Assist with the implementation of a new regulatory information management system (RIMS).
* Manage, track, and file all required SAE reports in accordance with Agency guidelines.
* Review change controls and provide Regulatory Assessment, where needed.
* Ensure regulatory commitments and submissions trackers are maintained.
* Assist with regulatory project management, including meeting management (distributing agendas, taking meeting notes, distributing meeting minutes/actions), updating regulatory timelines, risk assessments, etc.

**Required background and experience:**

* BS Degree required with 5+ years of direct experience in Regulatory Affairs within the bio-pharmaceutical industry. Strong knowledge of FDA, EU, and other ex-US regulatory authorities’ requirements.
* Strong regulatory writing capabilities and experience with preparing regulatory documents including new INDs, safety reports, Investigator Brochures, DSURs, IMPDs, CTAs, briefing packages and other regulatory submissions, in eCTD format.
* Experience with biologics drug development.
* Experience with early and late-stage drug development is a plus.
* Strong verbal and written communication skills; ability to clearly articulate regulatory viewpoints to a diverse audience.