**Title:** Manager, Regulatory Affairs
**Hiring Manager:** SVP, Regulatory Affairs & Quality
**Function:** Regulatory
**Location:** Waltham, MA

**Position Summary:**

The Regulatory Affairs Manager is responsible for supporting the development and execution of regulatory strategies to ensure timely approval of products with favorable labeling that meets the needs of the business, markets, and patients. This role requires a solid understanding of global regulatory science, drug/biologic development processes, and the ability to collaborate cross-functionally to influence key stakeholders. This individual will work closely with cross-functional teams to contribute to the global regulatory strategy and ensure compliance with applicable domestic and international regulations.

**Key Responsibilities:**

- Contribute to the development and implementation of regulatory strategies to support product development and approval.
- Collaborate cross-functionally to ensure alignment of regulatory strategies with business objectives and patient needs.
- Support the preparation and submission of regulatory dossiers.
- Serve as a Regulatory Affairs representative on Product Development Teams and ensure effective communication of regulatory requirements.
- Support the planning and execution of health authority interactions, including preparation of briefing documents and meeting materials.
- Monitor changes in the regulatory environment and provide guidance to internal teams to ensure compliance.
- Contribute to the development and communication of regulatory strategies for assigned projects, ensuring appropriate documentation and review.

**Qualifications:**

- Science degree in a science-related field or equivalent experience.
- Experience in regulatory drug development.
- Experience in preparing for health authority interactions (e.g., Scientific Advice, Pre-NDA/BLA meetings).
- Strong understanding of regulatory processes and requirements within one or more therapeutic areas.
- Ability to evaluate regulatory risks and contribute to strategic decision-making.
- Excellent communication, collaboration, and organizational skills.
- Demonstrated ability to work effectively in cross-functional teams and manage multiple priorities.

**About Upstream Bio:**

Upstream Bio is a public company based in Waltham, MA. We are developing verekitug, the only known antagonist currently in development that targets the receptor for Thymic Stromal Lymphopoietin (TSLP). We have advanced this highly potent monoclonal antibody into separate Phase 2 trials for the treatment of severe asthma and chronic rhinosinusitis with nasal polyps (CRSwNP) and plan to initiate development in chronic obstructive pulmonary disease (COPD). Our experienced team is committed to maximizing verekitug's unique attributes to address the substantial unmet needs for patients underserved by today's standard of care. Learn more about us at upstreambio.com.

**Interested candidates, please contact:**
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