Title: Associate Director/Director, Regulatory CMC
Hiring Manager: Sr. Vice President, Regulatory & Quality
Function: Regulatory
Location: Waltham, MA

Position Summary:

The Associate Director/Director, Regulatory CMC will be responsible for leading the regulatory Chemistry, Manufacturing, and Controls (CMC) strategy for the company's biopharmaceutical products. This role involves collaborating with cross-functional teams to ensure compliance with global regulatory requirements and support the development, approval, and commercialization of innovative therapies. The successful candidate will provide expertise in regulatory CMC, guide submission strategies, and maintain regulatory documentation to support product lifecycle management.

Key Responsibilities:

Regulatory Strategy and Submissions:

- Develop and implement global regulatory CMC strategies for product development and registration.
- Lead the preparation, review, and submission of high-quality CMC sections of regulatory submissions (INDs, CTAs, NDAs, BLAs, MAAs, etc.).
- Ensure alignment of CMC activities with overall regulatory strategy and project timelines.
- Coordinate with internal teams and external partners to gather necessary data and documentation for regulatory submissions.

Regulatory Compliance:

- Monitor and interpret global regulatory CMC requirements and ensure compliance with applicable regulations and guidelines.
- Provide regulatory guidance to cross-functional teams, including R&D, Quality, Manufacturing, and Clinical teams.
- Lead the response to regulatory agency inquiries and deficiency letters related to CMC aspects of submissions.
- Stay current with evolving regulatory requirements and industry trends in CMC.

Cross-functional Collaboration:

- Collaborate with internal stakeholders to ensure CMC strategies align with overall product development plans.
- Represent the Regulatory CMC function in project team meetings and regulatory agency interactions.
- Provide regulatory input and support to manufacturing and quality teams during process development, validation, and commercial production.

Documentation and Communication:

- Author, review, and approve CMC sections of regulatory submissions and related documents.
- Maintain accurate and up-to-date regulatory documentation and databases.
- Communicate regulatory CMC strategy, timelines, and risks to senior management and project teams.
- Train and mentor staff on CMC regulatory requirements and best practices.

Qualifications:

- BS or BA in scientific discipline
- Advanced degree (Ph.D., MS, or equivalent) in Chemistry, Pharmaceutical Sciences, Chemical Engineering, or a related field preferred
- 8-10 years of experience in regulatory CMC within the biopharmaceutical industry
- Proven track record of successful regulatory CMC submissions and product approvals.
- In-depth knowledge of global CMC regulatory requirements and guidelines (FDA, EMA, ICH, etc.).
- Strong project management, organizational, and problem-solving skills.
- Excellent written and verbal communication skills.
- Ability to work independently and collaboratively in a fast-paced, dynamic environment.

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:
Recruiting@upstreambio.com