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

Position Summary:

The Associate Director, Quality will be responsible for the development, management and continuous improvement of Quality Systems at Upstream to ensure its products and processes are compliant to regulatory, functional area and customer requirements. Partner with all areas of the business to understand and address their needs/issues. Interface with all areas of the business to elevate potential issues to management and drive continuous improvement efforts. Provide expertise and leadership in implementing a quality system management function for clinical and commercial products.

Key Responsibilities:

- Provide Expertise on implementation and maintenance of the Quality Management System (QMS), both electronic and paper based, including but not limited to SOPs, document control, product complaints, training, change management and quality event management (deviations and CAPAs)
- Administer documents for clinical and commercial operations that are compliant and fit for purpose.
- Facilitate continuous improvement initiatives aimed to increase efficiencies
- Support the inspection process for regulatory and partner audits and responses to audits.
- Support the vendor qualification process by performing vendor qualification audits, facilitating audit responses, and remediation activities
- Acting as a Clinical Quality resource on cross-functional teams as needed
- Ensure effective and timely Quality support of commitments to corporate timelines, milestones and regulatory requirements
- Partner with functional teams to identify, administer and implement optimized system designs for document management, change control, specifications, deviations and CAPAs and training.
- Manage Internal audit program and process improvements for Quality Systems.
- Actively influence and participate on Quality initiatives from a strategic compliance perspective.
- Draft and Review Quality agreements with partners and vendors.

- Participate on project teams as assigned.
- Responsible for input to the budget in the functional area.

Qualifications:

- Bachelor's degree in scientific discipline, operations research, operations management, business administration or a related field
- Advanced degree in a science related field and/or other appropriate knowledge/experience is preferred
- 8-10+ years' experience in the Pharmaceutical, Biotechnology or related industry.
- Extensive knowledge and understanding of global requirements for GXP and quality systems for clinical trial execution, and ability to apply said knowledge to make sound quality decisions.
    - Proven successful application of Clinical Quality principles in conjunction with cross-functional teams
- Exceptional attention to detail
- Excellent verbal and written communication skills, good interpersonal skills, ability to work collaboratively across functions.
- Excellent critical thinking skills to interpret external regulatory/compliance documents and internal metrics to propose appropriate mitigation.
- Working knowledge of software solutions for QMS.

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