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

Position Summary:

Upstream Bio is developing innovative therapeutics in inflammation. We are a nimble company with solid financial backing that has raised $400M from high-quality investors. We are developing a monoclonal antibody targeting validated biology and are focused on our two Phase 2 studies in asthma and chronic rhinosinusitis with nasal polyps (CRSwNP) in 2024. Our offices are in Waltham, MA. We have a hybrid working model, with Tuesdays-Thursdays in the office and Mondays and Fridays flexible to work remotely if desired.

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.
- Manage the vendor qualification process.
- 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 manufacturing and supply, and ability to apply said knowledge to make sound quality decisions.
- 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.