

Title: CMC Project Manager

Hiring Manager: Vice President, Technical Operations

Function: Technical Operations

Location: Waltham, MA

Position Summary:

The CMC Project Manager will support Technical Operations for Upstream Bio's verekitug program. Responsibilities include supporting the team to advance the program to meet major milestones, and coordination and operational support of manufacturing and analytical activities conducted at CDMOs. Additionally, this role will interact with Program Management, Clinical Operations, Regulatory, Quality, external CROs, and cross-functional teams to identify dependencies for CMC activities related to technical development and manufacturing. This individual will also be responsible for tracking timelines, technical milestones, CDMO deliverables, and data to support regulatory filings. This role requires a strong background in pharmaceutical project management and technical expertise in CMC processes to ensure alignment with regulatory requirements and organizational goals.

The successful candidate will report to the VP, Head of Technical Operations, and will be responsible for the following:

Essential Functions

- Provide technical project management and operational support for Technical Operations by attending and supporting the facilitation of technical CDMO meetings, maintaining timelines, keeping track of major milestones, and ensuring deliverables are met on-time.
- Define and monitor progress on deliverables and maintain timelines and budgets in alignment with program milestones, leveraging project management best practices.
- Ensure successful execution such that development projects achieve goals, objectives, and deliverables to progress the program
- Actively manage the relationships, performance, and productivity of CDMO partners to ensure
 on time deliverables and milestones are met, and escalate appropriately if deliverables are not
 meeting timelines
- Assist with financial accruals and resource (financial and FTE) forecasting based on progress of activities
- Facilitate and communicate project activities and information flow with all internal and external stakeholders.
- Maintain and update the Technical Operations risk register, track action items against the identified risks, and communicate/document status/resolution periodically and as needed



- In partnership with Program Management, facilitate preparation and regular updates of CMC strategy in harmonization with the internal integrated program plan
- Coordinate regular CMC project meetings with concise agendas to effectively document, communicate and ensure commitment to actions and decisions.
- Participate in regular meetings with CDMOs, as appropriate, to ensure communication flow between internal and external groups.

Qualifications:

- **Education:** Bachelor's degree in Science or Engineering, or related field required; MBA, Master's degree or Ph.D. preferred.
- **Experience:** Minimum 5 years of experience in CMC project management or related field within the pharmaceutical or biotech industry.
- **Skills:** Strong project management skills, with proven experience in managing timelines, budgets, and cross-functional collaborations.
- **Knowledge:** In-depth understanding of drug development processes, regulatory requirements, and CMC activities, preferably with biologics
- **Certifications:** PMP or similar project management certification is a plus.
- Other Requirements: Excellent organizational, communication, and leadership skills, with a proactive and collaborative approach to problem-solving.

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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