Title: CMC Manager, Drug Substance
Hiring Manager: Christine Lin
Function: Technical Operations
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) 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.

We are seeking a CMC Manager to play a critical role providing strategic oversight of external contract development and manufacturing organizations. This person is primarily responsible for ensuring that timelines are achieved to ensure drug supply for clinical trials. Excellent organizational skills and written and oral communication skills are required, as is the desire and ability to work in a small, nimble, fast paced, and patient-focused environment.

The successful candidate will have a demonstrated track record of technical and project leadership. This is an excellent opportunity for a highly motivated self-starter and creative problem solver who has a strong desire to make an important contribution to the development of novel therapies. This is a high-profile position with the opportunity to innovate in an entrepreneurial and high growth organization.

Key Responsibilities:

- Oversight of contract development and manufacturing organizations (CDMOs) to ensure drug substance, drug product, and assembly/label/pack timelines are met.
- Review of CDMO documentation inclusive of batch records, protocols, and reports.
- Monitoring and evaluation of analytical in-process, release, and stability testing results.
- Management of deviations inclusive of manufacturing investigations and OOS/OOT results.
- Collaborate with quality and regulatory teams to ensure drug material meets cGMP standards.
- Coordination of domestic and international drug material shipments.
- Supervise process characterization and validation and tech transfers as needed between contract sites.
- Utilize knowledge of impact assessment and risk mitigation to contribute to technical operations strategy.
- Support the filing of documents, particularly reviewing manufacturing sections of IMPD/IND or related regulatory dossiers, and authoring responses to regulatory questions in partnership with Regulatory CMC.
- Assist in inspections of contract testing and manufacturing sites.

Qualifications:

- Bachelor’s degree in engineering, life sciences or related field. Advanced degree encouraged but not required.

- A minimum of 5 years of experience in biopharmaceutical/pharmaceutical industry, preferably with experience in monoclonal antibody manufacturing.
- Ideally 3+ years of experience managing CDMOs/third parties for cGMP manufacturing and testing.
- Detailed knowledge of ICH guidelines, current Good Manufacturing Practices (cGMP), and compendial (USP, EP, JP, etc.) requirements and standards for QC testing.
- Knowledge of biotechnology/pharmaceutical product development process including technical transfer, manufacturing, process development and characterization, analytical/assay development, regulatory filings, and clinical/commercial operations.
- Expertise in Microsoft suite (Project, PowerPoint, SharePoint, Word, Excel, Visio, Outlook). Experience with other PM tools a plus (e.g. ThinkCell, OnePager, Kidasa, Smartsheets etc.).
- Excellent oral and written communication skills, including presentation and facilitation skills, to effectively inform key updates & issues across all levels of the organization.
- Strong analytical, problem solving and critical thinking skills, including an ability to combine attention to detail with a big picture perspective.
- Ability to work effectively as an individual contributor in a global team, collaborate with external partners/CDMOs to complete projects and adjust priorities as required to meet evolving company needs and deadlines.