Title: Principal Scientist, Bioanalytical Sciences
Hiring Manager: Director, Bioanalytical Sciences
Function: Preclinical
Location: Waltham, MA

Position Summary:

Upstream Bio seeks a Principal Scientist, Bioanalytical Sciences who will lead the development and implementation of critical bioassays to support development programs and provide scientific and operational oversight of bioanalytical sample analyses.

The ideal candidate will represent the Bioanalytical function on cross-functional project teams. In partnership with project teams, they will provide bioanalytical scientific and operational leadership to drive robust and timely decision-making through all stages of clinical development.

Key Responsibilities:

- Provide leadership and represent the bioanalytical group on project teams, oversee assay development/validation/performance monitoring at CROs, and ensure on-time, high-quality delivery of data and reports supporting drug development.
- Coordinate CRO and vendor selection (e.g., quote, capability assessments, site audits), oversee contracts/SOWs process.
- Review and approve bioanalytical protocols, reports, and related documentation.
- Manage timelines for delivery of assays, data, and reports to support clinical studies and regulatory submissions.
- Ensure that work is completed with appropriate quality according to regulatory standards and guidelines.
- Keep informed of the latest regulatory guidelines for bioanalytical assays.

If interested, the position will provide an opportunity to

- Develop and oversee execution of bioanalytical strategy to ensure the scientific quality of data meets regulatory and scientific requirements.
- Gain experience in developing exploratory biomarker assays.
- Opportunity to learn and develop appropriate laboratory manuals, prepare bioanalytical sections of regulatory documents, and respond to agency inquiries.
- Understanding of PK and PD data interpretation and ability to work with PK and clinical pharmacology team to interpret PK/PD data.

Qualifications:

- M.S. in Immunology, Molecular Biology, Biochemistry, or related discipline with 8+ years of industry experience in bioanalytical method development, validation, and sample analysis in a regulated environment.

OR

- PhD in Immunology, Molecular Biology, Biochemistry, or related discipline with 6+ years of industry experience in bioanalytical method development, validation, and sample analysis in a regulated environment.

- Strong scientific background and in-depth technical expertise on the development, troubleshooting, and validation of bioanalytical assays for biological compounds (ELISA and MSD based).
- Subject matter expert in analytical platforms. Experience developing and implementing PK, antidrug antibody, and cell-based neutralizing antibody assays for antibody-based therapeutics.
- Experience in successful development and execution of clinical bioanalytical assays implemented from early to late phase clinical programs.
- Current knowledge of regulatory guidelines related to qualification and validation of bioanalytical assays.
- Knowledge and experience with budgeting and resource allocation is preferred.
- Excellent interpersonal, leadership, communication, and time-management skills.
- Desire to work within a fast-paced, innovative, and collaborative 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