Senior Scientist, Bioanalysis

Summary:

Inhibrx is a clinical-stage biotechnology company dedicated to helping people with life-threatening conditions through scientific innovation and excellence. We are looking for a bioanalytical scientist to support and strengthen bioanalysis throughout the Inhibrx clinical drug development pipeline. The successful candidate would be accountable for regulated bioanalysis in support of current and future clinical studies. This role will be responsible for overseeing external CRO vendor work in support of clinical PK/ADA/Biomarker bioanalysis and will provide scientific/technical expertise to guide outsourcing assays at CROs. The scientist will possess deep scientific knowledge and technical experience in method development, optimization, and troubleshooting. Applicants will have demonstrated first-hand industry experience and technical knowledge of Pharmacokinetic, Immunogenicity and Neutralizing Antibody assays for large molecule therapeutics, and the ability to manage CROs in the conduct of assays and sample analysis. This position reports to the Director of Bioanalysis and will collaborate with multiple functions and departments within Inhibrx, including Project Management, Finance, Translational, Quality Assurance, Clinical Development/Operations and Pharmacology.

Role & Responsibilities:

- Accountable for all aspects of outsourcing large molecule PK/ADA assay validation and clinical testing to qualified CROs and ensuring BLA regulatory compliance of testing executions.
- Conduct vendor outreach, provide RFPs and review project proposals and contracts.
- Serve as project manager and provide sponsor oversight for all aspects of external assay development, validation, and clinical sample testing. Track and resupply vendors with sponsor supplied critical reagents. Communicate timelines and ensure data deliverables are met.
- Review and approve bioanalytical focused study documentation. Assure Good Laboratory Practice and Good Clinical Practice compliance with all managed Clinical Bioanalytical processes. Ensure data quality and integrity of validation and sample data appropriate to the study level and end use.
- Contribute to the management of and interactions between clinical vendors, such as sample management labs, sample testing labs, and clinical CROs and data management. Review and provide technical input on sample collection and kit manuals, data transfer and import agreements.
- Share information and give input on study timelines to internal teams. Provide technical expertise/guidance during CRO discussions or assay troubleshooting. Navigate and overcome project hurdles to meet study deliverables. Participate in process improvements and develop best practices for bioanalytical functions.
- Serve as subject matter expert to educate stakeholders on rationale for bioanalytical strategies, assay design, and experimental progress. Participate in bioanalytical focused audits for companies/academic institutions/CROs being considered or actively contracted for GLP/GCLP work.
- Learn and employ existing internal tools for project tracking. Use and maintain sample management tools and processes to monitor and verify appropriate samples are received by CRO labs and support reconciliation and sample issues to ensure timely PK/ADA data analysis driving critical study decisions

Core Competencies:

- Working knowledge of current LBA bioanalytical method validation and sample analysis regulatory guidelines in US and EU regions (FDA, EMA, MHLW, ICH, etc.)
- Must be able to work under strict or accelerated timelines and with competing deliverables.

- Ability to work effectively in a team as well as independently.
- Self-starting, goal oriented and result motivated
- Proven ability to manage multiple bioanalytical projects simultaneously
- Sound problem-solving and critical thinking capabilities
- Possession of high-level communication skills, able to prepare and effectively share scientific presentations

Required Education & Experience:

- Required BS or MS in chemistry/biochemistry or closely related field; minimum 8 years relevant bioanalytical experience in a biotech, pharma, and/or CRO setting.
- Extensive experience with managing external bioanalytical testing as Sponsor representative or working at the Principal Investigator level in a Contract Research Organization is critical and requires full GCLP understanding. Skilled in conducting bioanalytical research especially for overseeing the running of clinical samples, documenting data, and report writing/review following the regulatory requirements. Adept and comfortable with making data impacting decisions by relying on past experience, technical knowledge and regulatory expectations.
- Knowledge and experience of critical reagent preparation, characterization, and management is a must.
- Knowledge and experience with advanced methods in large molecule pharmacokinetics and immunogenicity assays including experience in the validation of ligand binding and cell-based assays using ELISA, MSD, and enzymatic based methods. Hybrid LC-MS, Gyros, flow cytometry, IHC and biomarker bioanalysis is beneficial.
- Understanding of current regulatory guidance and industry landscape, white papers and common practices pertaining to bioanalytical method validation and sample analysis is required. Experience with regulatory agencies interaction is a plus.
- Ability to travel periodically to industry conferences and CRO sites as well visits to Inhibrx's San Diego office if based remotely.

Benefits:

- 100% Employer-paid medical, dental, vision, and long-term disability insurance (eligible upon start)
- 5% 401(k) match (eligible upon start)
- Annual tuition reimbursement (eligible after 1 year of employment)
- Unlimited paid time off

Location: La Jolla, CA, remote considered

Job Type: Full-time

Contact: Nicole Anastassopoulos at nicole@inhibrx.com