



JOB DESCRIPTION

Job Title: Senior Scientist or Associate Principal Scientist, LBA Platforms	GLP Role: May serve as Principal Investigator
Segment: Bioanalysis & Biomarkers	
Line of Business: Crystal Bio Solutions	
Team: LBA Bioanalysis & Biomarkers	
Reports to: Senior level (management) Staff	Location: Pleasanton, CA
Position Type: Full-Time	Salary Range: \$120,000-\$165,000
Position Summary: <p>Crystal Bio Solutions is a CRO providing global-standard services in GLP/GCLP bioanalysis and biomarker. Our clients include multinational pharmaceutical companies and biotech companies.</p> <p>The Bioanalysis & Biomarkers Department specializes in Method Development, Method Validation, GLP/GCLP Bioanalysis for PK, immunogenicity and biomarkers. The team has successfully supported non-GLP, GLP (non-clinical) and GCLP (clinical) projects. The role is responsible for providing bioanalytical support for both pre-clinical and clinical projects and partnering with our clients for project success.</p>	

Key Responsibilities:

- Independently propose assay design and/or strategy, develop, validate, conduct, and troubleshoot bioanalytical methods, including PK, Immunogenicity (ADA and NAb) and Biomarker, for GLP/GCLP sample testing and data reporting. Present and interpret data internally and/or externally as needed.
- Serve as the Principal Investigator responsible for interaction with the client from the study design to scheduling, conducting, reporting, and transferring data. Ensure responsiveness to the client, timely delivery, and overall customer satisfaction.
- Serve as Subject Matter Expert (SME) for LBA (ELISA multimode reader & Meso-Scale Discovery (ECL)).
- Author and/or review key regulatory documents, validation plans and reports, laboratory data, and technical reports.
- Provide oversight of the laboratory, mentor junior staff, and collaborate to keep improving operational excellence.
- Assist in establishing and improving policies, procedures, work instructions and SOPs.
- Understand and adhere to corporate standards regarding code of conduct, Environment Health & Safety (EHS), and GLP/GCP/GDP compliance.
- Perform other related duties as assigned.

Qualifications & Educational Requirements:

- Ph.D., M.Sc., M.A., B.A., in Biology, Immunology, Chemistry, Pharmacology, or other related scientific fields required, including a minimum of 4+(Ph.D.), 9+ (Master's) or 12+(Bachelor's) years of Pharma/Biotech/CRO experience.
- Hands-on experience and strong knowledge of GLP/GCLP bioanalysis.
- Experience in LBA-based Method Development, Validation for PK, Immunogenicity (ADA, NAb) and PD Biomarker assays.
- An extensive knowledge of Immunogenicity Method Development, Validation and Sample Analysis is highly desirable.
- Previous experience with flow cytometry and cell-based assays for NAb and biomarker applications is a plus
- Experience with Watson LIMS and in CRO environment is preferred.
- Supervisory experience in both project and talent (people) management is preferred.
- Ability to work independently and pay good attention to details.
- Ability to achieve objectives/timelines through collaborative efforts with co-workers, managers, and clients.
- Must be goal-oriented, compliance-ensured, quality-conscientious, and client-focused.
- Effective writing and communication skills.

★ The salary range represents the anticipated base pay for this position. Actual compensation may vary based on factors including, but not limited to, skills, qualifications, experience, education, and location.

★ As part of our recruitment process, we may use technology-assisted tools to support application review and improve efficiency. All hiring decisions are made by our team.

★ Crystal Bio Solutions is an equal opportunity employer. We are committed to creating an inclusive environment for all employees and applicants and do not discriminate based on race, color, religion, sex, gender identity, sexual orientation, national origin, age, disability, or any other protected status in accordance with applicable laws.