Crystal Bio Solutions
A Member of Crystal Pharmatech

JOB DESCRIPTION

Job Title: Manager / Director of Quality Assurance	**GLP Role:** Quality Assurance
Segment: Bioanalysis & Biomarkers	
Line of Business: Crystal Bio Solutions	
Team: Quality Assurance Unit	
Reports to: CEO	**Location:** Pleasanton, CA
Position Type: Full-Time	**Salary Range:** $120,000-$165,000

Position Summary:

Reporting directly to the CEO, the Director of Quality Assurance (QA) will be responsible for the development, management, and continuous improvement of quality systems ensuring compliance with Good Laboratory Practice (GLP), Good Clinical Laboratory Practice (GCLP), and other applicable regulatory standards for our bioanalytical GLP lab in Pleasanton, California.

This role ensures that facilities, equipment, personnel, and procedures meet all regulatory requirements and effectively supports nonclinical and clinical testing activities.

Key Responsibilities:

- Host client and regulatory inspections, including preparing and submitting responses to findings.
- Support regulatory activities across all BABM sites within the organization.
- Audit raw data, summary tables, and reports associated with GLP and GCLP protocols to ensure compliance with regulatory requirements.
- Maintain inspection readiness, including preparing and managing site-specific documentation.
- Establish and ensure compliance with GLP, GCLP, and applicable FDA and international regulatory standards.
- Develop and manage the company's Master Schedule.
- Create, administer, and maintain QA Standard Operating Procedures (SOPs), QA files, and QA audit logs.
- Process, archive, and maintain QA department inspection reports and supporting documentation.
- Monitor and interpret regulatory requirements to ensure alignment with business processes and procedures.
- Author and review SOPs and Statistical Analysis Plans (SAPs).
- Provide GLP and GCLP training to staff.
- Recruit, develop, and mentor QA professionals, fostering a culture of growth and excellence.
- Conduct and report inspections of internal facilities and audits of external vendors to assess compliance with regulatory standards.
- Establish and administer a company Risk Register.
- Identify and address regulatory compliance issues, providing guidance to other departments.
- Deliver monthly compliance status reports to Test Site Management (TSM), highlighting issues and corrective actions.
- Represent the QA function in company meetings.

Qualifications & Educational Requirements:

- BA/BS degree in biological/physical sciences required. Advanced degrees (MA, PhD) preferred.
- 10+ years relevant Regulatory Affairs experience in the Bioanalytical CRO space and/or biotechnology/ pharmaceutical industry or a combination of education and experience
- Able to provide regulatory leadership and guidance on cross-functional teams and work in a matrixed environment.
- A business leader, capable of strategic thinking, planning, and proposing innovative solutions to regulatory challenges.

★ 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.