**Position:**

**Director of Clinical QA**

**About the Company:**

Dren Bio (the "Company") is a privately held, clinical stage biopharmaceutical company focused on developing therapeutic antibodies for the treatment of cancer, autoimmune and other serious diseases. The Company's management team and scientific advisors have profound expertise covering the discovery and development of specially engineered antibodies. Dren Bio's pipeline encompasses a multitude of programs from its two distinct, wholly-owned technologies. The Company's lead development candidate, DR-01, induces antibody-mediated killing of a specific cell type known to play a key role in various hematologic malignancies and autoimmune disorders. In addition to DR-01, the Company has launched multiple programs from its proprietary Targeted Myeloid Engager and Phagocytosis Platform, a bispecific antibody-based technology that offers a novel mechanism of action focused on selectively engaging myeloid cells (antigen presenting cells) for the targeted depletion of pathologic cells and other disease-causing agents.

**Function:**

**Quality**

**Level:**

**Director**

**Location:**

**Foster City (Remote candidates may be considered)**

**Reporting Manager:**

**VP of Quality**

**About the Opportunity:**

This critical position will collaborate with internal clinical and nonclinical functional groups and external parties including consultants, contract auditors, CRO/Service Provider personnel, and Investigator Sites to promote a high level of quality and consistency across all Dren development programs. This includes a risk-based approach to Quality Management for all Dren programs. Additionally, this position will independently manage domestic and international risk-based audits of Investigator Sites, clinical vendors, study databases, partners or collaborators (as applicable). The Director of CQA will also support internal Dren quality systems with the creation, review, and adherence to company policies, and procedures and adhering to GxP requirements.

**Role and Responsibilities:**

- Maintain expert up-to-date knowledge on applicable regulations that govern the conduct of clinical trials, ICH GCP guidelines and other GxP regulations and industry guidance and ensure the information is integrated into Quality and Clinical processes.
- Support the development and maintenance of CQA controlled documents and procedures that comply with ICH GCP standards and applicable regulations.
- Create and execute annual audit plan to ensure GCP compliance and adherence to study protocols by vendors, Investigator sites, study databases, and internal clinical team.
- Author and/or review procedures to support the Quality Management System, with an emphasis on clinical quality processes, clinical operations and clinical development functions.

- Collaborate with clinical functional groups (e.g., Clinical Operations, Data Management, etc.) to provide GCP and regulatory compliance support at the study execution level. This includes Clinical Study Execution Team (CSET) membership and participation.
- Perform review of clinical trial documents with a focus on compliance, regulatory requirements, and risk (study and company levels). The study documents include but are not limited to: Study Protocol and amendments, ICFs, Investigator's Brochure, Annual Reports (e.g., DSUR), CSRs, and other study level documents (e.g., study plans, subject recruitment materials).
- Conduct gap analyses and risk assessments for critical study level activities that may impact subject safety and/or the quality and reliability of data.
- Lead or support audits and investigations to evaluate non-compliance, root cause identification, and report results to Dren management. Ensures timely completion of comprehensive reports and communication of observations to auditees, impacted functional groups, and Dren management.
- Ensures audit corrective and preventive action (CAPA) plans adequately address audit observations and identified root causes, including effectiveness checks where appropriate.
- Provide leadership and support for Inspection Readiness activities and initiatives, and for the preparation, conduct, and response periods of Regulatory Authority Inspections.
- Escalate compliance issues to QA Management and other relevant leadership as needed in a timely manner.
- Develop, and/or support GxP tasks or Continuous Improvement initiatives as needed.
- Manage the workflow of CQA consultant Auditor(s), and as applicable, manage junior CQA staff.
- Build positive professional relationships to support learning, open communication, collaboration, and teamwork.

**Education, Experience and Qualification Requirements:**

- Minimum of a Bachelor of Science (B.S.) degree in a scientific, life science, or medical/technical discipline.
- Minimum of 10 years' experience within the pharmaceutical industry with at least 8 years of experience in a GCP or CQA quality role, with increasing levels of responsibility.
- Minimum of 5 years' experience in leading or independently performing CQA audits (Vendor qualification/routine/for-cause, Investigator Site, Gap Assessment, TMF, CSR, etc.), and audit CAPA management.

**Core Competencies, Knowledge and Skill Requirements:**

- Knowledge of Computer System Validation requirements in association with CQA audits.
- Effective communication skills (written and verbal).
- Ability to build and sustain positive relationships with colleagues, internal stakeholders, and external partners by being transparent, reliable, and delivering on commitments.
- Demonstrated ability to influence areas not under direct control to achieve objectives and effectively communicate challenging goals and objectives.
- Ability to create innovative solutions to problems, while integrating stakeholder input and feedback.
- Ability to manage multiple priorities and aggressive timelines.
- Highly responsible, self-motivated professional with enthusiasm and passion for the company's mission.
- Proficient with various Microsoft and other computerized tools: MS Word, Outlook, Excel, PowerPoint, etc.
- Expert knowledge in ICH GCP guidelines and FDA regulations

**Salaries, Benefits and Other Employee Perks:**

Dren Bio strongly believes in investing in, and rewarding, its employees. This philosophy is embodied in the Company's total rewards program, which includes competitive cash compensation, equity incentive awards, and employer sponsored benefit offerings. The base pay range for this position at commencement of employment is expected to be between $190,000 and $225,000 per year. At Dren Bio, pay ranges are determined by role, level(s), and location. The range displayed in this job posting reflects the minimum and maximum new hire pay for candidates located across all United States job markets. Within the range, individual pay will be determined by work location and additional factors, including job-related skills, experience, and relevant education or training. During the hiring process, Dren Bio's Human Resources department can share more about the specific pay range based on the market location of the candidate.

**Employment Practices:**

Dren Bio is an equal opportunity employer. Employment decisions are based on merit and business needs. Dren Bio will not discriminate against any job applicant because of race, color, national origin, ancestry, gender, sexual orientation, age, religion, creed, physical or mental disability, gender identity, medical condition, pregnancy, marital status, veteran status, or any other characteristic protected by federal, state or local law.

**Interested Applicants:**

Please send resume and cover letter to careers@drenbio.com