BioClin THERAPEUTICS

## Director/Senior Director, Quality Assurance

BioClin Therapeutics, Inc. is a privately-held biotechnology company developing biologics for medical conditions where there has been no approved or satisfactory therapy. Our lead program is a human monoclonal antibody, known as vofatamab (B-701), that targets and blocks the activity of FGFR3 (fibroblast growth factor receptor 3) and is being developed as a treatment for metastatic bladder cancer.

**Summary:**
BioClin is seeking a Director/Senior Director, Quality Assurance to lead and manage the Quality Assurance function and GxP compliance, including clinical and GMP manufacturing, validation and regulatory submissions. Responsibilities include establishing and executing quality plans including some direct audit activities, developing and updating policies and quality system elements related to GxP activities in support of global development of biologic therapeutics. The Director/Senior Director, Quality Assurance will establish, maintain and ensure effectiveness of quality programs and documentation to assure compliance in a GxP international regulatory environment and provides GxP guidance in Quality related areas with adherence to global regulatory and statutory guidelines. This key leadership role will support the design, implementation and maintenance of QA and compliance programs including, but not limited to an SOP system, batch record review/release, training program, CAPA/deviations, and internal and external audits at clinical sites and clinical and commercial suppliers. This position reports to the Chief Operating Officer and is based in our Bay Area office and must be able to work effectively in a fast-paced, small company environment.

**Responsibilities:**

- Develops and maintains Quality systems to insure compliance to GMPs and other applicable regulations.
- Manages and provides quality oversight for GMP QA Operations through oversight of external vendors including review of batch records for manufacturing and labeling/packaging operations to insure timely batch release of clinical trial materials (drug substance and drug product) for clinical trials.
- Ensures products are manufactured and tested and dispositioned in compliance with SOPs and applicable regulations.
- Partners with contract service providers and CMC to insure timely closure of deviations, OOS, investigations, complaints, and implementation of appropriate corrective actions.
- Develops product complaint system and interacts with the contracted complaint vendor team as appropriate.
- Conducts and provides oversight for GxP compliance auditing program to fulfill regulatory requirements.
- Reviews and approves GMP documentation such as batch records, analytical test methods, process and method validation protocols and reports, stability data product specifications and change controls.

- Contributes to material and finished product stability programs, transfer of validated methods to routine use and support of validation of methods.
- Supports GMP/GCP risk profile process and mitigation.
- Leads the GxP vendor qualification and oversight process and acts as subject-matter expert in GCP and GMP.
- Establishes and maintains Quality Agreements with contract service providers.
- Interacts and develops relationships with contract service providers' quality leaders through audits, project teams, and established one-on-one relationships.
- Establishes and maintains quality assurance policies, procedures and controls to meet quality and regulatory requirements.
- Provides input and advice around Quality Control systems within the business.
- Provides expertise and guidance to collaborating departments in interpreting and implementing government and agency guidelines to assure GxP compliance.
- Develops and implements quality systems and metrics to drive continuous improvement.
- Develops audit plans and conducts internal and external audits to ensure vendors are appropriately qualified.
- Directs the company global training programs.
- Develops and implements Quality Assurance policies and standards to maintain corporate regulatory compliance.
- Identifies gaps and improvement opportunities within the Quality system and communicates changing compliance requirements with senior management throughout the company.
- Supports regulatory agency inspections of sponsor, GCP sites and GxP contract service providers.
- Ensures compliance with corporate policies and procedures as well as US and global healthcare laws and regulations.
- May hire, develop, and manage internal and contract Quality staff dependent on the business needs.
- Performs other responsibilities and special projects as required.

**Requirements/Qualifications:**

- Bachelor's degree (or equivalent) in related field, with an advanced degree preferred.
- Minimum of ten years of Quality Assurance biologics experience in the biopharmaceutical industry, including at least five years of management experience; oncology drug development experience highly preferred.
- Experience providing QA/QC oversight for outsourced biologics manufacturing setting for clinical/commercial products is essential.
- Requires a thorough knowledge of biological pharmaceutical development, including manufacturing, clinical and analytical services.
- Proven knowledge of current US and ex-US regulatory guidelines, industry practices, and experience implementing quality systems in a regulated environment are required, as is experience with regulatory interactions preferably with FDA, EMA and PMDA.
- Leadership experience in GxP vendor management and oversight is critical.
- Requires proven experience with internal, vendor, and regulatory auditing and audit management, and complaint management.
- Knowledge of risk management, mitigation, and controls is essential.
- Experience with electronic filing, document management systems is essential.
- Requires excellent written and verbal communication and interpersonal skills.

- Demonstrated ability to collaborate and influence effectively across all levels and functions of the organization.
- Excellent strategic thinking and problem-solving skills.
- Must be highly organized and have good time management skills.
- Must be detail-oriented, with an ability to perform critical review of various types of documents.
- Demonstrated ability to multi-task, work independently, prioritize effectively, and meet goals in a deadline driven environment.
- Solid proficiency in Microsoft Office Suite, including Outlook, Word, Excel and PowerPoint.
- Ability for domestic and international travel (up to 25%).

BioClin Therapeutics provides excellent compensation and benefits, including medical/dental/vision insurance for employees and dependents, Flexible Spending Accounts, paid time off, paid life insurance, short-term and long-term disability coverage, and a 401(k) retirement plan with employer match.

To apply, please send your resume to HR@bioclintherapeutics.com.