

Associate Director or Director, Quality Assurance

Company

Visterra is a clinical stage biotechnology company committed to developing innovative antibody-based therapies for the treatment of patients with kidney diseases and other hard-to-treat diseases. Our proprietary technology platform enables the design and engineering of precision antibody-based product candidates that specifically bind to, and modulate, key disease targets. Applying this technology to disease targets that are not adequately addressed by traditional therapeutic approaches, we are developing a robust pipeline of novel therapies for patients with unmet needs.

Visterra's exciting pipeline includes VIS410, a human monoclonal antibody designed to offer truly broad-spectrum treatment of influenza A that is currently in clinical trials; VIS513, a monoclonal antibody to treat all four serotypes of dengue virus; VIS649, a monoclonal antibody in development as a treatment for Immunoglobulin A nephropathy, and several other early stage candidates targeting infectious diseases, cancers and kidney disease.

Visterra is a wholly-owned subsidiary of Otsuka America, Inc., which is a U.S. holding company and a wholly owned subsidiary of Otsuka Pharmaceutical Co., Ltd. of Japan. Visterra has approximately 70 employees and is in Waltham, Massachusetts.

Summary

The Associate Director or Director of Quality will be responsible for reviewing and tracking external GXP activities to provide proactive quality oversight of contract organizations across the supply chain while also developing and overseeing internal quality systems. Visterra is seeking a proven leader with a broad-based knowledge of pharmaceutical development and direct expertise in quality operations in a GMP environment. The successful candidate will take a leadership role in all GXP quality assurance activities at Visterra. This is a full-time position located at Visterra's offices in Waltham, MA.

Responsibilities

- Ensures overall Quality and Compliance oversight for GXP activities internally and with contract manufacturing, clinical supply chain and nonclinical and clinical partners.

- Establishes and maintains internal Quality Management Systems (including Quality policies, GXP training, Vendor Audit Program, CAPA management, and others) and ensures alignment with global policies and procedures.
- Designs and oversees the administration of internal GXP training programs.
- Represents Visterra to the Otsuka (Visterra's parent company) Global Quality Leadership Team. Interfaces with Otsuka Global Quality for incorporation of Otsuka global policies and SOPs.
- Understands and applies phase-appropriate quality standards for clinical development programs.
- Oversees GXP quality systems, operations and vendors including quality agreements, document control, deviation reporting, training, and more.
- Develops and manages internal and external audit programs including performance or oversight of audits and satisfactory closure of audit findings inclusive of CMOs, CTLs, CROs and investigator sites.
- Reviews and approves GMP documentation including but not limited to: master records, deviations, change controls, CAPAs, development reports, stability protocol/reports, and product specifications.
- Reviews and approves clinical study related documentation such as oversight plans, pharmacy manuals, filing plans, and randomization schemes.
- Effectively coordinates with supply chain, manufacturing, quality control, regulatory affairs and clinical operations partners for clinical study execution.
- Oversees Clinical Quality Assurance activities beyond audit management to include review/approval of study related documents (e.g. oversight plans, pharmacy manuals, filing plans, randomization schemes and others). Manages/conducts external quality audits of clinical sites, clinical and preclinical vendors, CMOs and other manufacturing vendors. Manages/conducts internal audits to ensure compliance with policies, procedures, GXP requirements and guidelines.
- Effectively coordinates with internal and external partners to support the manufacture, packaging, release, distribution of clinical trial materials. Assures compliance of drug product, documentation, and data related to the manufacturing, packaging, labeling, and testing of clinical drug and biologic products with GMP, SOP, IND/IMP, CTA and other relevant regulatory requirements.
- Creates key quality metrics for tracking and trending data related to GCP activities, reports metrics and significant quality incidents to senior leadership.
- Maintains a contemporary knowledge of current regulatory requirements, industry trends, standards and methodologies as they relate to GXP quality systems in the US and the European Union.
- Represents company in quality related matters in written and oral communications with FDA, EMA, and other regulatory agencies.

- Plans and prioritizes for resource allocation to execute the responsibilities of the QA function.
- Mentors career growth and development of junior members of the Quality team.
- Performing other duties as required.

Requirements

- Bachelor's degree in a scientific or engineering discipline required, higher degree preferred.
- 15+ years working in a GXP environment in a leadership role in Quality Operations.
- In-depth knowledge of GMP regulations for biologic products.
- Working knowledge of GCP.
- A track record of successful responses to inspections by FDA/EMA is a plus.
- Analytically strong with great attention to detail and excellent organizational skills.
- An ability to effectively collaborate cross-functionally across all levels of the organization.
- A proven ability to meet deadlines.
- A creative, collaborative approach to problem solving.
- Occasional travel is required to perform vendor audits and oversee GMP manufacturing.
- Enjoys and thrives in a multi-tasked and hands-on environment.
- The ability to work independently, meet deadlines and prioritize work effectively.
- An ability to think critically and strategically, communicate effectively across broad spectrum of audience both internal and external, clearly articulate complex subject matter, and express excellent written skills.

Visterra provides equal employment opportunities to all employees and applicants for employment and prohibits discrimination and harassment of any type without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws.

For consideration, please submit a cover letter and resume to careers@visterrainc.com.