Visterra

Title **Associate Director, Analytical Development and Quality Control; Pharmaceutical Sciences and Technology**

Location Waltham, MA

About Visterra

Visterra, Inc., is an innovative biotechnology company that uses its Atomic Interaction Network technology to identify unique disease targets and design effective first-in-class antibody-based therapeutics. Visterra's technology offers a new approach to the well-established pharmaceutical market for complex diseases, with the ability to identify new targets and engineer novel antibodies to be broadly effective in combating complex diseases with growing global unmet medical 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 being development as a treatment for Immunoglobulin A nephropathy, and several other early stage candidates targeting infectious diseases, cancers and kidney disease. Visterra was acquired by Otsuka in August 2018, becoming a wholly-owned subsidiary while retaining operations in Waltham, MA.

Job Description

The Associate Director, Analytical Development/Quality Control (AD/QC), reports to the Vice President of Pharmaceutical Sciences and Technology (PST), and is responsible for all aspects of AD/QC to progress biological molecules from early development through to clinical trials and product licensure. The Associate Director will collaborate with Research to design analytical methods for transfer to CRO and CMO partners. The Associate Director will be accountable for developing, qualifying and transferring specifications and analytical methods for drug substance and drug product characterization and GMP release. This role will also

Specific responsibilities for this position include:

- Direct analytical assay transfer, development, qualification and validation in collaboration with CROs and CMOs. Direct reference standard programs including characterization, stability, comparability and trend performance.
- Provide AD/QC support for early phase studies at Visterra, identify and propose critical quality attributes (CQAs) for candidate selection and provide feed-back mechanism from PST to Research. Monitor CQAs and identify relationships with process performance, toxicology and clinical outcomes.
- Establish and justify Drug Substance (DS) and Drug Product (DP) specifications and ensure process and method performance is in line with specifications. Verify release testing data and issue DS and DP Certificates of Analysis. Monitor QC release and stability assay performance, identify assay related issues, trouble-shoot atypical data, ensure remediation and optimization of assays.
- Define and approve phase appropriate stability studies, review analytical data and trends, identify atypical results and initiate investigations.
- Lead QC investigations at CMOs for OOT/OOS and atypical data, generate and follow Visterra SOPs for AD/QC activities. Review in-process and process development data at CMO, identify AD/QC issues and initiate investigations with QA and MFG.
- Contribute to authoring CMC sections of regulatory submission documents.

- Manage analytical development scientist(s) and contribute to department leadership.

Position Requirements

Experience

The candidate must have at least 12 years of combined industry related clinical or commercial biotechnology experience. Expert knowledge of analytical methods/QC as part of GMP manufacturing and DS/DP stability testing.

Education

A Bachelors, Masters or PhD Degree in chemistry, biological, biochemistry, biochemical engineering or related field within biotechnology.

Skills/ Abilities

In depth understanding of analytical methods for assessing biological products such as cell based assays, flow cytometry, ELISA, compendial methods, particle analyzer, mass spectrometry, and chromatography.

Experience with statistical software packages for data analysis.

Established manager of people in direct and/or matrix management roles.

Experience leading analytical method validation, qualification and transfer to internal or external testing laboratories.

Working knowledge of cGMP requirements, QC testing, ICH regulations and regulatory submission contents.

Ability to work in a fast-paced and dynamic environment with changing priorities, and flexibility to support multiple development programs simultaneously.

Ability to problem solve using innovative thinking and good decision making.

Skilled in customer relationships and collaboration/teamwork as team leader and team member.

Excellent written and verbal communication skills.

Ability to lead innovation, change and drive for results.

Willingness to travel occasionally (approximately 20%) to CMO and partner sites.

Manager VP, Pharmaceutical Sciences and Technology