Title **Senior Scientist, CMC; 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 recently acquired by Otsuka, becoming a wholly-owned subsidiary while retaining operations in Waltham, MA.

Job Description

The Senior Scientist, CMC, reports to a Senior Director within the Pharmaceutical Sciences and Technology (PST) team and is responsible for supporting CMC activities to progress biological molecules from early development through to clinical trials and product licensure. The Senior Scientist is accountable for supporting and leading process development, technology transfer and manufacturing of Visterra's pipeline molecules (specifically biologics). The Senior Scientist works closely with internal partners in Quality Assurance, Analytical and Quality Control and Regulatory as well as with external partners at Contract Manufacturing sites.

Specific responsibilities for this position include:

- Assist in the identification and selection of contract manufacturing partners for cell line development, drug substance manufacturing and drug product manufacturing.
- Author and review "Requests for Proposals" for contract services.
- Author and review process descriptions, facility fit assessments and other technology transfer documentation.
- Review and approval of transfer and manufacturing documentation such as batch records, standard operating procedures, sample plans, protocols and summary reports.
- Provide on-the-floor support of manufacturing operations and collect and monitor key process performance data and results. Able to troubleshoot and resolve process and/or production deviations.
- Prepare presentations of manufacturing data, project plans as needed for internal review and external discussions.
- Design and review development, optimization and characterization studies. Review process data and author/review summary reports.
- Represent PST team in internal meetings and in external meetings with contract partners.
- Perform work with limited direction.

Position Requirements

Experience and Education

A Bachelors, Masters or PhD Degree in a scientific or engineering discipline with a focus in a biochemical engineering field (e.g., chemical or biochemical engineering) is required. The

Senior Scientist must have at least 10 years experience beyond BS (e.g, BS plus 10 years, MS plus 8 years, PhD plus 5 years) working in the biotechnology industry, preferably within a process development or clinical manufacturing environment.

Special Skills/ Abilities

Knowledge of and experience with

- cell culture and fermentation operations such as seed and inoculum expansion, microbial and mammalian cell production, media preparation, aseptic processing, and centrifugation and filtration harvest methods, and/or
- purification operations such as chromatography operations, column packing, ultrafiltration, diafiltration and viral filtration, and/or
- drug product operations such as formulations, filling, lyophilization and drug delivery devices.

Knowledge of GMP manufacturing principles and documentation.

Ability to conduct experiments, review manufacturing documents and data and present to cross-functional teams. Lead strategy for process development, characterization and validation in a phase-appropriate manner.

Ability to set project priorities and work independently to achieve team and individual goals

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

Excellent written and verbal communication skills.

Ability to travel occasionally to conferences and global manufacturing sites (approximately 10-20% time required for travel).

Manager Pat Vollmer