Title **Manufacturing Engineer, 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 Manufacturing Engineer, 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 Manufacturing Engineer is accountable for supporting process development, technology transfer and manufacturing of Visterra's pipeline molecules (specifically biologics). The Manufacturing Engineer 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.
- Assist in authoring and reviewing "Requests for Proposals" for contract services.
- Assist in authoring and reviewing process descriptions, facility fit assessments and other technology transfer documentation.
- Support the review and approval of transfer and manufacturing documentation such as batch records, standard operating procedures, sample plans, protocols and summary reports.
- Participate in parameter and control range specification. Collect evaluate and present process data.
- Provide on-the-floor support of manufacturing operations and collect and monitor key process performance data and results. Assist in troubleshooting and resolving process and/or production deviations.
- Prepare presentations of manufacturing data, project plans as needed for internal review and external discussions.
- Assist in design of development, optimization and characterization studies. Review data and author/review summary reports.
- Represent PST team in internal meetings.

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 Manufacturing Engineer must have at least 5 years combined education and experience (e.g, BS plus 5 years, MS plus 3 years, PhD plus 1 year) 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.

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 Senior Director, Pharmaceutical Sciences and Technology