



<b>Title</b>	<b>Senior Scientist, Analytical Development, CMC; Pharmaceutical Sciences and Technology</b> <hr/>
<b>Location</b>	Waltham, MA
<b>About Visterra</b>	<p>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 an innovative 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 in 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.</p>
<b>Job Description</b>	<p>The Senior Scientist in Analytical Development (AD), CMC, reports to the Associate Director of Quality Control and Analytical Development (QC&amp; AD) and supports analytical activities to progress molecules from early development through to clinical trials and product licensure. The scientist is accountable for analytical development and characterization of Visterra's pipeline molecules. The scientist will work very closely with internal QA, QC, MFG, and Clinical teams as well as with GMP Contract Test and Manufacturing partners.</p> <p><u>Specific responsibilities for this position include:</u></p> <ul style="list-style-type: none"><li>• Provide technical and analytical support to research and development teams to support lead candidate identification and development</li><li>• Generate/review standard operating procedures for characterization of biologics for use at Visterra, train lab members and manage transfer of methods to CMOs</li><li>• Identify and stay current with new analytical technologies and methods for characterization of biologics</li><li>• Perform characterization and degradation studies on lead candidates, critically assess findings and share results with cross-functional teams</li><li>• Manage time-lines and milestones for analytical assessment of lead candidates, ensure smooth transfer to CMOs/CTOs</li><li>• Identify contract test organization (CTOs) for assay transfer, develop protocols for assay qualification and validation, review and approve data</li><li>• Prepare presentations for external partners and internal meetings and represent analytical and CMC issues</li><li>• Provide analytical support for investigations at CTOs and CMOs, generate hypothesis, critically review results</li><li>• Travel to CTO sites may be required as needed to assist with site audits (10-20%)</li></ul>
<b>Position Requirements</b>	<p><u>Experience</u></p> <ul style="list-style-type: none"><li>• Writing and approving SOPs, qualification protocols and reports, assessing data to support specification and stability assessments.</li><li>• Working in a GMP environment to support manufacturing/testing/release of biologics or small molecules</li></ul>

- Managing direct reports and identifying and working with vendors/CTOs/CMOs in an outsourced model.

### Education

A PhD degree in chemistry, biochemistry or a related analytical scientific discipline and a minimum of 5 years of relevant experience, or an MS with 8 years or a BS with 10 years of experience.

### **Preferred Special Skills/ Abilities**

Hands-on experience with some of the following protein purification methods; HPLC, UPLC, CE-SDS, SDS-Page, protein purification, CEX, iCIEF, LC-MS, Glycan analysis, ELISAs, and cell-based potency assays

Experience with statistical and analytical software e.g. SPSS, JMP, Excel, SAS, Chemstation, SoftMax, PRISM, and Empower.

Strong interest in innovative strategies for analysis and control of new modalities of biologics

Experience with trouble-shooting assays, creative problem-solving, method transfer and mentoring junior team members.

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

Skilled in managing cross functional relationships and collaboration as a team member.

Experience with writing reports, generating cross-functional presentations, working with external teams and maintaining time-lines

Excellent written and verbal communication skills