Scientist/Senior Scientist, Process Development

Krystal is seeking a highly motivated Scientist/Senior Scientist to lead the Process Development Group. The successful candidate will provide expertise and scientific leadership for design, development, and optimization of processes for viral vectors and biologics production. Responsibilities include Upstream and Downstream Process development and execution, scale-up studies, characterization studies, and authoring transfer documents for tech-transfer to the clinical manufacturing site(s). This individual is expected to work independently and interact with Contract Manufacturing Organization as needed. The successful candidate will prioritize assignments to meet departmental and organizational goals.

Primary Responsibilities

- Develops scalable, robust, high yielding, and economically viable processes for production and purification of biologics and viral vectors like recombinant HSV1
- Leads efforts to evaluate resins, filters, and analytical methods pertinent to purification development activities, as needed.
- Performs experiments using Clarification systems, Chromatography instruments, and TFF systems.
- Executes process monitoring and control strategies for robust process design
- Ensures scalability of unit operations during process development
- Designs and executes experiments, analyzes and interprets data, to make process improvements, and further design next studies
- Provides person-in-plant support for cGMP manufacturing of pre-clinical and clinical study materials
- Authors Standard Operating Procedures, technical reports, process descriptions
- Supports the execution of start-up, commissioning, and maintenance of equipment and processes
- Reviews process descriptions and batch records during tech transfer
- Keeps current with advances in upstream and downstream processes for production of large molecules
- Prior experience in managing a small group of technical staff preferred

Skills, Knowledge, and Abilities Required

- B.S., M.S., or PhD in Biological sciences, Biotechnology, Chemical engineering, Chemistry, or related fields. B.S. requires a minimum of 6 years of relevant experience.
- Hands-on experience in developing and improving scalable upstream processes in Process development setting
- Familiarity with FDA guidance and quality systems preferred
- Experience in a cGMP environment preferred

- Familiar with good laboratory practices including equipment maintenance, and the use of biochemical analytical tools to acquire in-process data preferred
- Excellent record keeping abilities to adequately document process development data
- Detail-oriented and able to prioritize assignments
- Strong verbal and written communication skills and ability to communicate within the organization as well as externally
- Able to travel as needed