Director of Process Development

Who we are:

Krystal Biotech, Inc. is using gene therapy to develop effective and novel treatments for skin diseases. Our goal is to make a meaningful difference in the lives of underserved patient populations with debilitating skin diseases. We work to accomplish that through scientific innovation, operational excellence and believe that "nature operates in the shortest way possible". (Aristotle)

Our vision:

We strive to be the leader in the development of novel and proprietary "off the shelf" gene therapy products to fight some of the world's most serious skin diseases.

Our mission:

To develop transformative, innovative, and science-based HSV gene therapy products and processes to dramatically improve people lives.

Job Description Summary:

The Director of Process Development is responsible for leading a team of scientists & engineers responsible for developing the clinical/commercial process(es) for our most advanced HSV-based (viral vector) therapeutic candidate. Once developed, the Director of Process Development will oversee efforts to characterize and optimize that process as well as the development of subsequent manufacturing processes for candidates advancing through the pipeline. This role reports to the Vice President of Process Development & CMC Operations.

The Director of PD will be responsible for upstream (cell culture & virus production) and downstream (harvest & purification) activities with the goal of eventually developing a singular "platform" process for the entire HSV program portfolio. The Director of PD will also oversee in-process analytical method development and testing. Lastly, the director of PD will likely oversee the formulation and drug production filling and finishing operations, although specific responsibilities in this area will be determined based on candidate experience.

The individual chosen for this position will work in close partnership with the Head of Manufacturing, and/or external parties to support GMP manufacturing of clinical supplies, including generation of master and working cell and viral banks necessary to support process development and clinical manufacturing. The Director of Process Development will also work closely with the Krystal R&D group to facilitate seamless movement of projects through the development continuum.

The focus of this leadership role is to employ innovative approaches to ensure Krystal develops and implements a state of the art HSV manufacturing platform process for clinical and commercial viral vector products, working in close partnership with internal and external experts to realize this goal. To this end, the Director of PD will keep current on new technologies, and regulatory requirements that may have an impact on the company's development and manufacturing plans.

The ideal candidate is:

- A demonstrated self-starter who is excited by the possibility of gene therapy and values the direct impact he/she will have on the lives of our patients.
- Someone who deeply understands "end to end" viral vector bioprocessing strategies to include the current "state of the art" analytical tools used to evaluate them.

- An excellent leader with experience managing teams of high-performing PD scientists/engineers.
- Has a deep technical understanding of HSV (preferred) or viral vector manufacturing platforms (in general).
- A demonstrated record of scientific expertise (i.e. publications, presentations, etc.)
- Able to work with multiple stakeholders to develop strong cross-functional teams.
- A highly motivated and ability to take a proactive approach on the job.
- An excellent communicator with relationship building skills and an ability to work effectively in a matrix environment to gain the buy-in of others.
- Experienced with developing and delivering presentations to management and clients.
- Has a solid understanding of business and financial fundamentals.
- Willing to challenge the status quo and provide creative solutions to identified challenges.
- Has a PhD in a life science and 5-7 years of experience in viral-vector related PD, an MS and 10 years of experience, or a BS/BA and 12 years of experience

Specific responsibilities include but are not limited to:

- Assessing and refining the strategy for Krystal's HSV-based gene therapy PD group with an immediate focus on completing the actual process development and "locking" the process to be used for GMP runs and PPQ (process validation) of our initial candidate.
- Working closely with other necessary department heads to develop a tech transfer plan for processes coming from PD and moving GMP manufacturing.
- Working closely with the VP of Process Development and MFG Operations to determine a robust Process Performance Qualification (PPQ) protocol strategy, to include generation of appropriate acceptance criteria.
- Responsible for the all stages process development (FIH, CPD, MSAT) for all programs within the pipeline.
- Oversees the development and implementation of an (upstream and downstream) process monitoring/control strategy program using appropriate statistical guidelines.
- Oversees the development and implementation of drug substance and drug product release specifications.
- Oversees the development and implementation of a microbial control strategy.
- Leads authoring efforts for specific CMC sections of regulatory filings (including INDs, BLA's, and formal responses to regulatory inquiries).
- Drives innovation from ideation to realization for process improvements, including definition of technology roadmap, justification of projects, and developing implementation plans.
- Support business cases and CAPEX justifications for capacity expansion, facility build-outs and acquisitions.
- Participates in planning to ensure alignment between resource availability and project pipeline.

All interested applicants should submit their resume to dmaheu@krystalbio.com.

Krystal Biotech, Inc. is an Equal Employment Opportunity and Affirmative Action Employer. Qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender perception or identity, national origin, age, marital status, protected veteran status, or disability status. Headhunters and recruitment agencies may not submit resumes/CVs through this Web site or directly to managers. Krystal Biotech, Inc. does not accept unsolicited headhunter and agency resumes. Krystal Biotech, Inc. will not pay fees to any third-party agency or company that does not have a signed agreement with Krystal Biotech, Inc.