Associate Director/Director of Analytical Development

Who we are:

Krystal Biotech (NASDAQ: KRYS) is a gene therapy company based in Pittsburgh, Pennsylvania. We are developing innovative and transformative gene therapy medicines to dramatically improve patient lives affected by debilitating skin diseases. We work to accomplish this goal through scientific innovation, operational excellence, and the belief that "nature operates in the shortest way possible" (Aristotle).

You can learn more about Krystal Biotech, Inc. at www.krystalbio.com

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's lives.

Associate Director/Director of Analytical Development Position Description:

Associate Director/Director of Analytical Development will be responsible for in-house and out-sourced analytical activities in support of drug substance and product manufacturing and testing. Experience with biologics products is required; experience with viruses, gene therapy products or vaccines a plus.

Responsibilities will include, but are not limited to, the following:

- Provides strategic leadership and technical expertise in analytical method development for release and stability testing of drug substance, raw materials, intermediates and drug product
- Drive analytical development planning, development and execution of timelines to meet project goals, working with project teams
- Leads analytical method qualification and validation and transfer of methods of all in-process and release assays to commercial QC for release testing
- Applies scientific driven thinking to the development of scientifically sound, well understood, and robust analytical methods. Examine scientific literature for new methods to quantitate and characterize viral vectors and process related impurities.
- Assess and define requirements for test methods to meet corporate objectives, consistent with regulatory requirements and relevant Pharmacopeia
- Responsible for leading qualification/validation of analytical methods
- Develop phase-appropriate quality control strategy for drug substance and drug product and manage product stability study programs
- Prepares and delivers technical reports, documents, batch analyses, analytical methods, reference standard, etc. for regulatory submissions

Requirements:

- PhD in biological sciences with 7+ years or BS/MS with 15+ years' gene therapy/biologics analytical development/validation experience in the pharmaceutical industry
- Excellent scientific knowledge in analytical methodology
- Strong analytical development knowledge and experience in assay validation
- Effective verbal and written communication skills, experience managing CROs and CMOs.
- Extensive knowledge of cGMP and applicable FDA, EMA and ICH guidance, and familiarity with the USP and other compendia.
- Ability to navigate and be successful in a fast-paced, matrixed work environment

All interested applicants are required to submit their CV/Resume and Cover Letter to pagarwal@krystalbio.com and skrishnan@krystalbio.com. Please note, applications submitted without resumes and cover letter will not be accepted.

Krystal Biotech, Inc. is an Equal Employment Opportunity and Affirmative Action Employers. 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.