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:

Krystal Biotech, Inc. is seeking a Vice President of Clinical Development to lead parallel development programs in different dermatological and pulmonary genetic disorders set to enter the clinic in the next 12-18 months. Reporting to the Chief Operating Officer, the Vice President of Clinical Development will be an integral member of the Krystal Biotech leadership team, contributing significantly to the advancement of programs into and through the clinic, and be a part of a fast-paced cross-functional team to bring these therapies through development. The direct responsibilities of this position will cover Phase 1 through Phase 3 and post-approval activities, expanding and advancing the Company's programs from early clinical trial development to proof-of-concept and commercialization. This Vice President will be in a high profile and high impact position, responsible for executing and delivering on critical clinical milestones, and will also be integral to the clinical development strategy. The individual hired for this position will, therefore, have significant influence shaping the future of the Company. The individual will have the opportunity to be promoted to Chief Medical Officer in 1-2 years based on performance.

The position is based in our Pittsburgh, PA office.

Specific responsibilities include but are not limited to:

- Leading clinical development programs from the late preclinical stage, to registration and completion of post-approval commitments.
- Work cross-functionally with Clinical Operations and/or vendors to successfully execute clinical trials and natural history studies. These activities may consist of coordination, collection and analysis of clinical data and reporting, and providing ongoing medical monitoring for clinical trials, including assessment of eligibility criteria, toxicity management, and drug safety surveillance.
- Manage the preparation and/or review of data listings, summary tables, study results, study reports, and clinical/regulatory/safety documents, investigator brochures, and clinical development plans.
- Interact with global regulatory agencies and have responsibility for authoring and/or reviewing relevant Pre-IND, IND, and BLA sections and generating responses.

- Close collaboration with academic institutions associated with the clinical development program.
- Engage with thought leaders, investigators, cooperative groups and other experts in constructive scientific and clinical dialog around study design, study conduct, and interpretation of clinical results.
- Must be able to critically evaluate and understand the unmet medical needs in various rare dermatological, pulmonary disorders, outcome measures, treatment options, etc..
- Partner with internal and external key stakeholders to develop manuscripts for publication in peer-reviewed journals and preparation of presentations for scientific conferences as well as for clinical study investigator meetings and expert clinical advisory meetings.
- Collaborate with Medical Affairs in developing medical slide decks, educational materials, publication strategy.
- Represent Krystal Biotech, Inc. externally where necessary through publications, presentations at scientific meetings and congresses, both domestically and internationally.
- Work collaboratively to assist with business development and pipeline activities.
- Ensuring adherence to regulatory requirements of study conduct and industry standards of Good Clinical Practice.

The ideal candidate is/has:

- Ten (10) years of clinical development experience, including designing and managing clinical trials, authoring clinical trial protocols and study reports, and developing clinical development strategy.
- MD with biopharmaceutical industry experience and translational medicine experience. Experience in rare disease and clinical pharmacology preferred, with experience in pediatrics, dermatology, pulmonary, gene therapy or internal medicine a plus.
- Demonstrated leadership in a clinical development capacity and team building skills as well as the ability to perform effectively in a dynamic and evolving environment.
- Excellent working knowledge of FDA and EMA regulations and expectations, Good Clinical Practice, ICH guidelines, and clinical drug development. Experience in representing the sponsor in front of regulatory agencies and obtaining regulatory approval preferred.
- Successful submission of INDs and submission of marketing approval-directed filing(s) (BLAs, NDAs, and MAAs) is preferred.
- Ability to create an active network with KOLs, key research centers, patient advocacy groups and a variety of patient care organizations.
- Understanding of statistics and data management considerations for clinical trial design and scientific communications
- Knowledge of medical monitoring of clinical trials required (e.g., responding to questions about patient eligibility and protocol waivers; review of safety parameters; receiving and processing SAEs, including the composition of SAE narratives; and IND expedited safety reports)
- Strong communication (oral, written) skills to present internally and at scientific meetings and author medical documents and scientific publications
- Ability to collaborate with internal and external stakeholders and diverse workforce within a cross-functional matrix environment
- Exceptional organizational, analytical, critical thinking, problem-solving abilities and strong attention to detail while working on multiple projects in a fast-paced, dynamic start-up and scaling environment.

All interested applicants are required to submit their CV/Resume and Cover Letter to 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.