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 was 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.

Job Description Summary:

Reporting to the COO, the Senior Director of Clinical Development will have worldwide responsibility for the preparation and implementation of Krystal's clinical development programs and pharmacovigilance. The individual who assumes this position will interact with multiple levels of management within Krystal and with external stakeholders in the medical and scientific community and global regulatory authorities. The Senior Director of Clinical Development will be responsible for the short and long-term clinical development strategy of Krystal.

Specific responsibilities include but are not limited to:

- Lead the delivery of clinical development activities for several clinical stage programs in the Rare Diseases Unit and ensure consistency with clinical development strategy for regulatory approvals, reimbursable medicines, and successful lifecycle management.
- Responsibility for advancing Phase 1-Phase 4 clinical programs from clinical study design and execution through interpretation of data and publication.
- Integrate the scientific rationale, regulatory requirements, product development plan, and commercial goals to build a solid strategic framework for the Clinical Development Plan (CDP).
- Research and deploy innovative approaches to clinical trials, including use of digital and electronic approaches.
- In conjunction with clinical operations, establish efficient clinical development timelines, incorporating key decision points and Go/No Go criteria for the CDP.
- Contribute to the development of strategic commercial initiatives and business development activities.
- Ensure rigorous adherence to Good Clinical Practice and ICH Guidelines.
- Provide credible medical representation in the academic medical/scientific community.
- Contribute to the development of clinical sections of regulatory documents like clinical protocols, investigators' brochures, briefing books, safety updates, IND/BLA submission documents, responses to questions from health authorities.

- Representing Krystal externally and building key relationships with the medical community, investigators, key opinion leaders, contract research organizations, regulatory authorities, and clinical sites.
- Ensure that the scope of work, planning, expectations and project timelines are clearly communicated and aligned with clinical development team members and all key stakeholders.
- Conduct staff performance reviews and develop planning for the Clinical Development team and optimize clinical resources through recruitment and training of medical and scientific talent, as needed.
- Drive goal setting for clinical development in alignment with corporate goals.
- Preparation and monitoring of the clinical budget in conjunction with R&D.

The ideal candidate:

- MD degree required. Clinical experience in pediatrics, dermatology, pulmonary or internal medicine a plus.
- Ten (10) years of clinical development experience, including leading clinical development teams.
- Experience of pharmaceutical development in rare diseases and clinical pharmacology preferred.
- Demonstrated leadership and team building skills as well as the ability to perform effectively in a dynamic and evolving environment.
- Ability to collaborate with a diverse workforce within a cross-functional matrix environment.
- Strong communication (oral, written) skills to present internally and at scientific meetings and author medical documents and scientific publications.
- 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 preferred.
- 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).
- Demonstrated experience and expertise in the primary authorship of clinical trial protocols and clinical study reports.
- Understanding of statistics and data management considerations for clinical trial design and scientific communications.
- Experience in obtaining global regulatory approvals and/or expertise in translational/early clinical development for innovative medicines preferred.

Interested applicants should submit their CV/Resume and Cover Letter to jsuskin@krystalbio.com. Please note, applications submitted without resumes and cover letters will not be accepted.

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 website 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.