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:

Krystal Biotech is seeking a highly motivated individual to author high-quality documentation to support the implementation of our quality system, GMP manufacturing area, and quality control laboratory.

Specific responsibilities include but are not limited to:

- Work with internal teams to obtain an understanding of the product and the documentation requirements.
- Produce high-quality documentation that meets applicable standards and is appropriate for its intended use.
- Initiate and update GMP manufacturing associated documentation, such as clearing procedures.
- Provide oversight of daily Quality Assurance functions which include review and approval of records generated by manufacturing and quality control documents.
- Provide support for updates on standard operating procedures and associated forms.
- Provide QA support of site cGXP documentation related to the operation of gene therapy manufacturing facility/laboratory to ensure compliance with regulatory agencies, and oversee continuous improvement of company's quality assurance and compliance functions.

The ideal candidate is/has:

- Minimum of a bachelor's degree (Biology or related Life Science) with 3+ years of relevant quality systems experience in the biotech or pharmaceutical industry.
- Prior experience in the gene therapy field is desired.
- Background that includes knowledge/experience in GMP, GLP, and GCP.
- Strong knowledge of GMP and ICH requirements.
- Must be a self-starter and capable of working with minimal oversight.
- Must be able to handle multiple roles and work in a fast paced and changing environment, and know how to prioritize activities appropriately.
- Excellent oral and written communication skills.

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.