QA Associate

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

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

- 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.
- Provide 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.
- Initiate and update quality system standard operating procedures, and associated forms.
- Initiate and update quality control documentation, such as SOPs, material monographs (specification and testing documents), and test methods.
- Initiate and update GMP manufacturing associated documentation, such as cleaning procedures.

Requirements and Preferred Qualifications:

- 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 of GMP, GLP, GCP, USP, and/or ICH requirements.
- Must be a self-starter and capable of working with minimal oversight.
- Excellent writing and editing as well as written/oral communication skills are required.

Interested applicants should submit a CV and Cover Letter to jfantini@krystalbio.com.