

QA Manager

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 lead the manufacturing Quality Assurance activities of our quality system and GMP manufacturing area.

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

- Work with the supply chain and manufacturing teams to facilitate material management (purchasing, receipt, inventory, storage, sampling, and issuance) and batch record execution.
- Provide QA support for master batch record generation and batch record issuance, execution, and review.
- Provide QA support for facility and manufacturing related qualification documents (DQ/IQ/OQ/PQ, Calibration, PM, Cleaning of systems and equipment).
- Provide QA review of facility, supply chain, and manufacturing SOPs.
- 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.
- Initiate and update quality system standard operating procedures, and associated forms.
- 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 5+ 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 their CV and Cover Letter to jfantini@krystalbio.com

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.