QC 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 be a leader in our Quality Control laboratory. The qualified candidate will be responsible, in collaboration with Krystal’s Analytical Sciences group, to oversee the transfer and validation of both common and new, state-of-the-art, analytical methods to be used for characterization, validation, and release of Krystal’s clinical and commercial products. Additionally, the individual will partner closely with Manufacturing to coordinate environmental monitoring and to ensure consistent and timely lot release. Finally, the individual will, in collaboration with Quality Assurance, develop specifications and coordinate release of raw materials for GMP Manufacturing.

The ideal candidate is/has:

- Minimum of a Bachelor’s Degree (Biology, Biochemistry, Chemistry, or related Science) with 7+ or an MS with 5+ or a PhD with 3+ years of relevant quality control and/or EM experience in the Biotech or pharmaceutical industry.
- Demonstrated ability to effectively receive and validate various virus-based analytical methods from process development into GMP Quality Control.
- Experience managing QC laboratory operations.
- Experience with ELISA, PCR, cell-based bioassay, imaging techniques, environmental monitoring, raw material testing, etc.
- Experience managing outsourced analytical testing (to include all commonly used product safety/contamination tests).
- Experience hiring and managing laboratory personnel.
- Ability to perform bench level testing as required.
- Highly organized, detail-oriented, self-motivated, and goal driven. Must be a self-starter and capable of working with minimal oversight.
- Able to work and communicate effectively on teams to progress projects.
- Background that includes knowledge/experience of GMP, GLP, GCP, USP, and/or ICH requirements.
- Prior experience in the gene therapy field is desired. HSV-based GT preferred.
- Excellent writing and editing as well as written/oral communication skills are required.

Specific responsibilities include, but are not limited to:

- Manage and perform transfer and validation of analytical methods into the QC laboratory.
- Assist QA in developing raw material release specifications and provide expertise, development, and validation of related testing methods.
- Oversee development of EM program for a new GMP, aseptic processing manufacturing facility.
- Develop, with the QC Director, governing Quality Control policies, procedures, and practices that ensure compliance with regulatory agencies and oversee continuous improvement of Krystal's quality control functions.
- Assist with QC laboratory design, buildout, equipment selection, and equipment qualification.
- Manage QC testing workload to support Krystal's clinical and commercial operations.
- Manage QC generated data in GMP compliant manner.
- Oversee drug substance/drug product stability program.
- May perform bench level testing as needed for method transfers and/or release testing as resource availability and workload demand.
- Oversee implementation of a "LIMS" system in the QC lab.
- Hire and develop QC staff to support Krystal's clinical and commercial operations.

Interested candidates should submit their CV/Resume and Cover Letter to dreitsma@krystalbio.com.