Quality IT Specialist

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:

Krystal Biotech is seeking a highly motivated IT Specialist. We are looking for individuals to support the quality system from the IT perspective. The IT Department plays an integral role in supporting the Quality System and is responsible for company-wide cGMP quality systems support, implementation and process improvements.

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

- Identify, implement, and manage various phase appropriate quality software systems (e.g. Document repository; LIMS; Trackwise; Electronic signatures), for an emerging biotechnology company, in accordance with 21 CFR Part 11 and FDA, MHRA, and cGMP standards.
- Develop and maintain ISMS for ISO 27001 certification.
- Develop and implement the software development life cycle.
- Coordinate the planning, implementation, validation, and maintenance of all information technology products.
- Maintain, manage, troubleshoot and upgrade computer systems and servers for performance and security related issues.
- Coordinate the set-up of data services, as well as phone, computer, and printer installation.
- Troubleshoot information technology-related issues for both hardware and software.
- Performs Risk Management, Risk Mitigation and Risk Reduction using PDCA and FMEA.
- Interact with internal departments to and provide user support for a variety of applications and resolve complex issues in a timely manner.
- Must understand and participate in prevention and be able to improve systems and procedures as applicable
- Must be able to work in a fast paced and changing environment and know how to prioritize activities appropriately

Requirements and Preferred Qualifications:

- Minimum of a Bachelor's Degree in a related computer science, business or other related field from an accredited college or university with 2+ years of relevant experience in the biotech or pharmaceutical industry
- Application support & development work in a cGMP or other regulatory environment is desired, with experience with 21 CFR Part 11 and FDA and MHRA standards.
- Must be a self-starter and capable of working with minimal oversight.
- Excellent oral and written communication skills.

All interested applicants are required to submit their CV/Resume and Cover Letter to jfantini@krystalbio.com.