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, Inc is seeking a highly motivated Computer Systems Validation (CSV) Analyst. This role will have responsibility to support CSV activities of systems and programs requiring system and/or software qualification and testing. This will include the validation of new GxP computer systems used in the QC labs and within Manufacturing production. The analyst will be responsible for the development of validation documentation, including User Requirements Specifications (URS), Functional Requirements Specifications and Test Protocols to ensure that the system is fit for its intended use.

Essential Functions:

- Provide support for Computerized System Validation such as analytical equipment and electronic systems to maintain a compliant state.
- Write, review and approve user requirement specifications, risk assessments, operation, SOPs related to computerized systems for compliance to regulatory requirements.
- Ensure adherence of computer systems to FDA 21CFR Part11 and Annex 11 compliance.
- Responsible for the timely execution of all systems implementations, software validations and instruments qualifications, in a compliant manner and in alignment with established quality and regulatory requirements.
- Maintains the computerized validation status as part of validation life cycle.
- Completes periodic reviews on computerized systems per established procedure.

The ideal candidate will have:

- CSV experience within an FDA / EMEA / GMP environment or within another highly regulated industry.
- 1-3 years of relevant work experience
- The ability to handle multiple projects and competing priorities with a proven track record of quality results
- Great communication skills both verbally and written.

- Analytical & Problem-Solving Abilities
- Attention to detail

Interested applicants should submit their CV/Resume and Cover Letter to clavey@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.