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 is seeking a highly motivated Process Validation Associate (1-2 years experience) or Engineer (3-7 years experience) to support process validation planning, design, and execution. This person will be responsible for risk assessments, process improvements, investigations, and other projects. They will also play a pivotal role in technology transfer and ensuring processes transition properly from site to site.

Specific responsibilities include but are not limited to:

- Partner with Process Development and Manufacturing to ensure upstream and downstream processes are well controlled.
- Apply QbD and traditional process validation principles to existing and new gene therapy products.
- Perform and document risk assessments to capture existing process knowledge and to identify gaps.
- Perform experiments (bench scale and manufacturing scale) to close gaps in process understanding and to support process development.
- Troubleshoot process and equipment issues to help ensure efficiencies in processes.
- Help implement a continuous improvement mindset to processes and departments.
- Produce high-quality documentation that meets applicable standards and is appropriate for its intended use.
- Work on development of new manufacturing facility to ensure proper transfer of technology and processes.
- Work with CMC counterparts to draft materials intended for the agency review.

The ideal candidate is/has:

- Minimum of a Bachelor's Degree (Chemical Engineering, Biomedical Engineering, or field) with 5+ years of relevant validation or engineering experience in the Biotech or pharmaceutical industry.
- Prior experience in the gene therapy field is desired.
- Background that includes knowledge/experience in GMP, GLP, and statistics.
- Strong knowledge of GMP and ICH requirements and QbD.

- Must be a self-starter and capable of working with minimal oversight.
- Must be able to handle multiple roles and work in a fast paced and changing environment and know how to prioritize activities appropriately.
- Excellent oral and written communication skills.

All interested applicants are required to submit their CV/Resume and Cover Letter to jsuskin@krystalbio.com. Please note, applications submitted without resumes and cover letter will not be accepted.

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.