Kite, a Gilead company, is a biopharmaceutical company engaged in the development of innovative cancer immunotherapies with a goal of providing rapid, long-term durable response and eliminating the burden of chronic care. The company is focused on chimeric antigen receptor (CAR) and T cell receptor (TCR) engineered cell therapies designed to empower the immune system's ability to recognize and kill tumors. Kite is based in Santa Monica, CA. For more information on Kite, please visit www.kitepharma.com.

Kite is seeking a highly motivated individual with fill finish and cryopreservation process engineering experience to work on innovative T cell therapy for cancer treatment. The Senior Engineer will demonstrate deep knowledge of fill finish and cryopreservation, develop robust processes for final drug product formulation, fill finish and cryopreservation for T cell therapy. The Senior Engineer will work with the Early Stage Product Sciences team to design, establish and scale-out cell therapy processes to support early phase clinical trials, manage equipment qualification and support process verification, draft and review protocols, production procedures, process development reports, and provide technical assessment and approval for engineering and process changes pertaining to fill finish and cryopreservation. The Senior Process Engineer will also participate in laboratory activities to support process development and process characterization of Kite's autologous T cell products.

Responsibilities include, but are not limited to:

- Identify proper final drug product formulation, container/closure system and develop robust fill finish and cryopreservation processes
- Advance early-stage pipeline products into clinical process format, and subsequently provide technical oversight and support of GMP clinical manufacturing operations
- Design and execute process development studies to develop a thorough understanding of operating and performance parameters pertaining to fill finish and cryopreservation

- Participate in technology transfers of new processes into GMP manufacturing operations
- Author and review technical documentation (batch records, SOPs, protocols & reports for FATs, SATs, IQ/OQ/PQ testing, and validation testing)
- Ensure successful manufacturing production runs by assessing risk, setting preventative measures in place, investigating and troubleshooting equipment and process issues

- Perform hands-on activities that support process development and process characterization, ranging from drafting procedures to execution of laboratory studies

Qualifications:

- A degree in Biochemistry, Chemical Engineering, Biotechnology or equivalent
- 5+ years of pharmaceutical process development and manufacturing experience in fill finish and cryopreservation
    - Cell culture or aseptic processing experience is required, experience in human primary T cell therapy is strongly preferred

    - Deep knowledge of cGMP manufacturing, regulatory requirements for pharmaceuticals and devices
    - Well-developed computer skills, proficient in JMP and other statistical software
- Ability to think critically, and demonstrated troubleshooting and problem solving skills
    - Excellent interpersonal, verbal and written communication skills
    - Ability to function efficiently and independently in a changing environment
    - Self-motivated and willing to accept temporary responsibilities outside of initial job description

Kite Pharma is an equal opportunity employer based in Santa Monica, CA. Kite Pharma offers the opportunity to be part of a successful, fast growing company in a cross functional and collaborative environment.

To learn more about us, please visit our website at www.kitepharma.com.

If you are interested in applying for this position, please email your resume to Eddie Lee at elee@kitepharma.com