

Sr. Scientist, Process Development

Reports to: Associate Director, Cell Therapy Tech Ops Process Development

Location: Houston, TX

Inquiries and Resumes should be sent to: careers@alaunos.com

About Alaunos

Alaunos is developing commercially scalable, cost-effective T-cell receptor (TCR) T-cell therapies based on its non-viral Sleeping Beauty gene transfer platform targeting solid tumors. The company has clinical and strategic collaborations with the National Cancer Institute and The University of Texas MD Anderson Cancer Center. For more information, please visit www.alaunos.com

Summary

The Process Development Scientist, Cell Therapy, Technical Operations, is responsible for carrying out hands-on internal laboratory experiments, process development, report writing, and pre-manufacturing identification of cell therapy raw materials, products and operations for clinical trials and eventual commercial sale, as well as assisting in the associated technology transfer to the cGMP setting.

Responsibilities

This position will coordinate with internal stakeholders to perform laboratory experiments and process development for Alaunos' cell therapy pipelines. The candidate shall possess strong technical and communication skills as well as substantial existing knowledge of cell processing equipment, analytical techniques, and previous experience working within a cGMP manufacturing environment.

Work with Alaunos personnel to develop and translate gene-modified T cell processes and methods to the cGMP environment. Design and execute experiments to define process conditions, minimize process variability, optimize process parameters, and identify critical process parameters. Aid in the execution of technology transfer protocols as well as validation protocols (IQ/OQ/PQ) for cell processing equipment. The technology transfer responsibilities will also involve periodic work in the cGMP manufacturing environment. Examples of specific job duties are as follows:

- Carryout laboratory experiments and developmental procedures
- Generate process analytical data and documentation for projects
- Create process and batch documentation and write summarizing reports
- Perform data analysis and trending for processes, stability and analytics
- Perform hands-on processing of blood products using a variety of cell processing equipment
- Evaluate process materials and methods for suitability, cost, and reliability in cGMP manufacturing operations
- Manage inventory in the laboratory to support process development activities
- Contribute supporting data and language for regulatory filings
- Managerial oversight of department

Education and Experience

The Process Development Scientist Cell Therapy Technical Operations will have a Bachelors or Masters in a cell biology, bioengineering, or related field and a minimum of 5 years in the biotechnology industry.

Knowledge, Skills and Abilities

- Proven track record of building and maintaining relationships with internal stakeholders for process and analytical development and GMP manufacturing
- Expertise in primary cell culture, specifically T cells
- Proven experience organizing and analyzing data for processes and analytics
- Experience with analytical methods development
- Experience with process development using automated equipment and platforms
- Established knowledge of cGMP, Quality Assurance, and FDA device/drug/biologics regulations
- Strong troubleshooting and problem-solving skills
- Self-motivated, ability to work well with cross-functional teams or independently in a dynamic and highly collaborative environment
- Well-organized with solid technical, written, and verbal communication skills, computer skills, and proven ability to multitask
- Attention to detail and strong quality ethos

Working Conditions

Some travel required (up to ~5%).

Alaunos is an equal opportunity employer. As an equal opportunity employer, we are committed to a diverse workforce. Employment decisions regarding recruitment and selection will be made without discrimination based on race, color, religion, national origin, gender, age, sexual orientation, physical or mental disability, veteran status or other non-job related characteristics or other prohibited grounds specified in applicable federal, state and local laws.