

Head of Technical Operations

Reports to: EVP, Operations

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 Head of Manufacturing is responsible for leadership of the manufacturing operations and associated logistics of the company's cell therapy programs, including managing operations of the internal cGMP manufacturing in Alaunos' Houston site. This person will work with corporate partners and internal and external stakeholders to develop the CMC manufacturing strategy and manage the execution of the manufacturing activities for the product portfolio.

Responsibilities

This position is a leading technical and managerial resource for manufacturing operations for Alaunos' TCR-T program.

- Lead manufacturing unit/team, providing technical and managerial guidance to all activities especially clinical manufacturing, process qualification and validation, and optimization of scheduling
- With operations team members, develop the technology transfer, scale-up and manufacturing strategies for cell therapy programs
- Manage internal and external manufacturing decisions to meet or exceed program goals and ensure compliance with FDA regulations
- Responsible for authoring CMC sections for submission to regulatory agencies
- Forecast and manage the manufacturing budget for the cell therapy programs
- Communicate/present manufacturing data to the broader technical team
- Provide oversight of GMP material supply and product logistics, managing personnel and IT systems to maintain operations.
- Provide oversight of facility and equipment selection/IQ/OQ and maintenance
- Responsible for manufacturing schedule, optimizing resources.
- Provide technical direction for the programs, including component and raw material specifications and vendors, drug substance specifications, processes and procedures; contribute advice on analytical methods, stability programs, release testing procedures, scale-up processes, SOPs and other controls for each of the Company's products, as appropriate for such products' stage of development.

- Provide leadership in planning and expanding manufacturing capacity, aligning it with clinical requirements. Work with team to optimize process flow as capacity is expanded.
- Perform gap assessments and establish risk mitigation strategies to ensure robust manufacturing processes. Develop new systems and processes as needed.
- Ensure that drug substances and drug products are of the quality required for their intended use and stage of development, incorporating internal quality standards, as well as cGMP and other drug regulatory requirements.
- Provide technical guidance for the CDMO or CMO selection. Evaluate, select and manage CMOs of key reagents, drug substance and drug product, as needed.
- Responsible for technical content of Quality Systems documents (batch records, SOPs, deviations, validation reports, etc.). Author such documents as needed.
- Provide input to research priorities for the programs
- Build and mentor the manufacturing, facilities and logistics team

Education and Experience

The Director will have a minimum Masters/BS in a cell biology, immunology or bio/chemical engineering field and a minimum of 7/9 years, respectively, in the biotechnology industry. Experience in cell therapy and manufacturing is required. Candidate should have experience managing CMOs.

Knowledge, Skills and Abilities

- Knowledge of cellular therapy, genetic modification of cells with viral or non-viral vectors. Non-viral expertise preferred.
- Proven experience in development of cell therapy bioprocessing and gene modification activities
- Proven understanding of the multiple issues that are necessary for the successful production, characterization, and formulation of biologics and cell-based products.
- Experience transferring product assets from research through development to early clinical phase manufacturing.
- Trouble shooting and problem-solving skills in cell and gene therapy field
- Understand technical and scientific knowledge of gene modified cell manufacturing concepts, critical process parameters, as well as cell therapy tools and operations.
- Proficient in basic understanding of blood sample processing, cell isolation, primary human cell culture, immunological assays (Cell phenotyping and characterization by FACS, ELISA, functional cell assays)
- Fluency in aseptic processing experience using human blood product and primary cells
- Knowledge of drug development and operations, cGMP, quality and regulatory
- Knowledge in QbD applications
- Experience with managing CMC issues and risk mitigation to enable filing successful IND's, NDA's, BLA's/MAA's. Emphasis/preference for early clinical stage experience.

- Experience building and maintaining relationships with internal (for example Clin Ops, RA, Quality) and external stakeholders, and CDMOs/CMOs used for process and analytical development, and GMP manufacturing
- Experience managing and mentoring team
- Experience leading in a multifunctional and matrix setting, with both internal and external stakeholders
- 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
- Proficient in Microsoft Office
- Attention to detail
- Must have ability to work assigned shift (day, night, holidays, and weekends)
- Must be comfortable with being fully gowned in PPE and working in a clean room environment, which is an enclosed, restricted space with an assigned pressure and temperature conditions.
- Must be comfortable with being exposed to human blood components
- Must be able to work near proximity to strong magnets

Working Conditions

Some travel required (up to ~25%).

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.