**Director, Manufacturing**

Reports to: EVP, Operations
Location: Houston, TX
Inquiries and Resumes should be sent to: careers@ziopharm.com

**About Ziopharm**
Ziopharm 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.ziopharm.com. Ziopharm is a public company (NASDAQ: ZIOP).

**Summary**
The Director, Manufacturing, is responsible for managing the manufacturing operations and associated logistics of the company's cell therapy programs, including operation of the internal cGMP manufacturing in Ziopharm's 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 resource for manufacturing operations for Ziopharm's TCR-T program.

- Lead manufacturing unit including process qualification and validation, clinical manufacturing and scheduling
- With leader of CMC Development and team, 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
- Oversight of GMP material supply and product logistics, managing personnel and IT systems to maintain operations.
- Manage manufacturing schedule, optimizing resources.
- Forecast and manage the manufacturing budget for the cell therapy programs
- 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 authoring CMC sections for submission to regulatory agencies
- Responsible for technical content of Quality Systems documents (batch records, SOPs, deviations, validation reports, etc.)

- Provide input to research priorities for the programs
- Build and mentor the manufacturing and logistics team

**Qualifications**

- Master's/BS in a cell biology, immunology or bio/chemical engineering field and a minimum of 7+ years preferred in the biotechnology industry.
- Experience in cell therapy and manufacturing strongly preferred.
- Candidate should have experience managing CMOs.
- 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
- Organized with solid technical, written and verbal communication skills, computer skills, and proven ability to multitask