Director, Quality Assurance

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 of QA will assist in leading the company's Quality program by providing support in assuring adherence to current GXP (Good Manufacturing Practice (cGMP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) compliance) with all regulatory statutes including state, federal, and international regulations, and company policies that govern the development of cell and gene therapies, drugs, biologicals, and other company products. The main focus of this role is to support GMP activities for on-site cell therapy manufacturing; support in GCP and GLP activities is also required. In addition, the Director of QA will be responsible for assisting in the development and maintenance of the company's Quality Systems, specifically around in house manufacturing; preparation and maintenance of Standard Operating Procedures (SOPs); oversight and participation in the internal auditing program; review and approval of batch-related documentation, including Quality Event review and product release.

Responsibilities
Establish and maintain the company's overall Quality System. This position will mainly support the QA GMP related activities but will also support the GLP and GCP activities as needed. Some of the main functions and responsibilities are outlined below:
Assure that activities conducted both internally and on behalf of the company are in compliance with applicable laws, regulations and company policies

- Verify that drug substance and drug product are manufactured according to cGMPs
- Manage the writing/reviewing process of Governance Documents (SOP, WI, Forms, Templates, etc.) and GMP operational documentation (MFG and QC)
- Recommend, create, implement, and update SOPs, as necessary, to improve processes, and support compliance
- Implement, track, and manage quality standards, systems, and metrics for maintaining regulatory compliance for on-site GMP operations
- Support improvements and maintenance of the Quality Management System (QMS), including ensuring the system is fully functional in GMP department areas while maintaining compliance with regulatory agencies
- Coordinate and conduct internal audits and report findings

- Lead potential FDA audits on behalf of company, as needed
- Support the CMC/manufacturing team with validation activities such as process, analytical, equipment, and IT systems
- Act as a compliance resource to provide guidance and assistance towards resolution of moderate to complex deviations, quality investigations, lab investigations, CAPAs and change control
- Use of Risk Assessment in quality systems processes
- Provide oversight/monitoring of GMP activities which includes internal and external (CMO, CDMO, and CTL), as appropriate
- Capable of working in a startup environment with the ability to multi-task, prioritize, and execute with minimal guidance

Qualifications

- Bachelor's degree in a scientific discipline or equivalent degree, and a minimum of 7-10 years of experience in a combination of quality assurance with minimum of 2-5 years in management. A broad understanding of the drug development process is required.
- Ability to lead and coordinate diverse team
- Ability to work with multiple departments for planning of activities, resolution of quality issues and for supporting clinical activities.
- Excellent communication skills, both verbal and written, including appropriate use of medical and scientific terminology
- Excellent interpersonal skills.
- Ability to work with internal and external teams and to work with partners
- The ability to simultaneously handle multiple project issues while dealing with time demands, incomplete information, or unexpected events
- Experience with cell therapy is a plus.
- Understanding of the drug and biologic development and commercialization process
- Understanding of manufacturing processes including terminology
- Understanding of clinical research process including medical and clinical terminology
- Understanding of non-clinical research process including terminology