ALAUNOS™ THERAPEUTICS

Quality Control Microbiologist Analyst II or III

Reports to: Associate Director, QA CMC
Location: Houston, TX
Inquiries and Resumes should be sent to: careers@alaunos.com

Summary

The QC Microbiologist Analyst II will support the Quality Control, Environmental Monitoring team in maintaining the cleanrooms for commercial manufacture for both At Rest and In Operation conditions. This role will be central in all processes associated with environmental monitoring and integral with environmental investigations, excursion report writing, and general upkeep of the microbiology department. Analyst will execute procedures and processes which governs a new quality control microbiology laboratory to support on-site operations, and activities performed by CMO/CRL, which are in compliance with all regulatory statutes including state, federal, and international regulations, and company policies.

Essential Functions and Duties

- Perform and support environmental monitoring program
- Execute microbiological assays for media, raw material, and product release when needed
- Coordination and performance of microbial isolations and identifications
- Maintenance of the laboratories, supplies, and equipment
- Writes reports and performs investigations for environmental excursions and deviations
- Complete data analysis and summary reports for scheduled trend reports
- Revises procedures and qualification reports through change control
- Maintains compliance with all required training and assists with training of fellow analysts
- Reviews, edits, completes, and/or revises data capture forms, logbooks, reports and SOPs in accordance with cGMP standards and compliant with written procedure
- Contribute with the design, development and implementation of quality control microbiology training programs and training other employees
- Participates in equipment start-up, commissioning, and validation activities, as needed
- Assist with the implementation/validation of onsite testing such as (sterility, endotoxin, and microbial ID)
- Ensures all tasks are performed in a manner consistent with safety standards

Additional Functions and Duties as Necessary

- Support in create general Quality Control systems and procedures to govern on-site testing for GMP manufacturing facility
- Support sampling plan, release, and retain program for incoming raw materials
- Assist in testing of samples and/or coordination of samples to Contract Testing Labs
- Participate and aid in the Stability Program for critical raw materials, in-process, DS or DP, as needed

Education and Experience

Bachelor's degree (BS) in a scientific discipline or related degree, and 2 to 7 years of direct experience in quality control in a cGMP environment. Ideal candidates will have cell therapy or biologics experience in on-site manufacturing.

Knowledge, Skills and Abilities

- General knowledge of both Analytical and Microbiology Quality Control requirements
- Displays effective communication skills (written and verbal)
- Able to multitask and support various projects and teams
- Strong organizational and time management skills
- Expertise with Microsoft Office; Word, Excel, and Microsoft Project
- Experience with electronic document management systems a plus
- Experience with an electronic compliance management system a plus
- Exhibits flexibility

Working Conditions

- Routine Laboratory and office conditions
- Position is an on-site role
- Periodic travel may be required between Houston sites

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