Metrology Specialist

Company Overview

OrganaBio is a Miami-based CDMO that manufactures clinical (cGMP) grade cells for cancer immunotherapy and regenerative medicine drug developers. OrganaBio's vision is to accelerate the development of these drugs by giving developers access to (i) fresh and scalable tissue supplies; (ii) cell isolation, purification, expansion and characterization services; (iii) process development services; and (iv) clinical manufacturing services. At OrganaBio, we empower our customers' people, process and products on their journey to commercialization. Our team is comprised of highly motivated individuals who thrive in a fast-paced environment and are adept (and like) to deal with different tasks within a work week. Medical, dental, vision and 401(k) benefits are included with full time posted positions.

Job Profile

OrganaBio is seeking a Metrology Specialist to contribute to the efficiencies of the OrganaBio's manufacturing facility, to include but not limited to, clean rooms and general laboratory areas, facility equipment and laboratory equipment, and to ensure the facility and support laboratories are operating in a functional and compliant manner, as stated in federal, state and other applicable regulations and standards.

Primary Responsibilities

- Assist with cleaning procedures implemented in the clean room and general areas of the GMP facility, including all applicable documentation.
- Manage asset/equipment lifecycle including, but not limited to receiving, installation, qualification, repair, maintenance, and cleaning.
- Support environmental monitoring of cGMP facility and support areas, as applicable, including applicable documentation.
- Support new equipment acquisition and problem-free operation.
- Coordinate repair and preventive maintenance work assignments performed by previously approved 3rd party vendors and contractors performing building maintenance, landscaping and janitorial work, and review work orders to ensure that assignments are completed according to the pre-established schedule.
- Support internal and external facility inspections and audits.
- Assist facility personnel with demonstrating facility capabilities to new and prospective customers
- Support new clients with all aspects of move-in and utilization of the facility, including day-to-day operations and troubleshooting, as needed
- Ensure established Standard Operating Procedures are followed to maintain equipment, automated systems and facility in compliance.
- Assist in generating new equipment and facility-specific protocols and standard operating procedures.
- Actively promote safety protocols and awareness. Demonstrates good safety practices at all times, including appropriate use of protective equipment. Reports and takes initiative to correct safety & environmental hazards.

Requirements

- High school diploma or general education degree (GED) required. Associates degree or Bachelor's degree with focus on business, engineering, technical or management areas preferred.
- Demonstrated proficiency with PC and/or PDA systems for work order system, email, and training.
- Demonstrated rack record in working in facility under GMP regulatory compliance.
- Familiarity with common GMP manufacturing and laboratory equipment, and practices.
- Experience with working with biotech manufacturing equipment, as well as equipment maintenance, and calibration.
- Familiarity with Good Documentation Practices.
- Fluent in English with strong communication (both written and verbal) and interpersonal skills.
- Demonstrated effectiveness in the ability to ensure quality service within the company, with business partners and customers.
- Ability to:
  - Quickly identify and address inefficiencies or malfunctions in equipment performance.
  - Manage challenging situations and recommend effective solutions to problems.
  - Effectively manage multiple tasks.
  - Effectively collaborate with internal and external teams and management.
  - Effectively communicate facility capabilities to prospective clients and develop valued relationships with current clients.

Employment Type

- Full-time

Applicants should send a cover letter and resume to Dr. Elina Linetsky elina.linetsky@organabio.com.

It is strongly preferred that successful applicants for positions are fully vaccinated against COVID-19.

OrganaBio is an Equal Employment Opportunity employer. OrganaBio prohibits any form of unlawful harassment or discrimination against applicants for employment or employees on the basis of any legally protected status entitled to protection under federal, state, or local law.

DISABILITY ACCOMMODATION FOR EMPLOYMENT APPLICATIONS OrganaBio is committed to providing reasonable accommodations to enable applicants with disabilities to have equal opportunity to search for a job opening or apply for a position. Any applicant requiring assistance with our career opportunities website or who needs an accommodation due to a disability, should send an e-mail to careers@organabio.com. This email address is not for general employment inquiries or correspondence. We may only respond to those requests that are related to the accessibility of the online application system due to a disability.