Facilities Manager

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

Leverage experience in facility management to bring operational efficiencies and excellence to OrganaBio's manufacturing facility and to ensure the facility and support laboratories are operating in a functional and compliant manner, as stated in applicable FDA, state and other applicable regulations and standards.

Primary Responsibilities

- Manage asset/equipment lifecycle including, but not limited to purchasing, receiving, installation, qualification, repair, preventive maintenance, and cleaning.
- Manager Facility systems / equipment lifecycles including, but not limited to qualification, repair, and maintenance.
- Support and clear understanding of a comprehensive environmental monitoring program in support of the cGMP Facility and support areas, as applicable.
- Maintain equipment and general and clean room use, preventive maintenance, and cleaning documentation, according to the GMP/GLP documentation practices.
- Maintain and update Asset Master Files, throughout the lifecycle of equipment that supports operations within the facility, including but not limited to new asset induction, installation, calibration / qualification / validation, preventive maintenance and decommissioning).
- Determine the capability of the general laboratory areas and cGMP facility clean rooms to provide the necessary support for new equipment (e.g. size, environmental temperature/humidity range, power requirements, and other utilities), and advise on renovations/modifications required to support new equipment acquisition and problem-free operation.
- Coordinate, oversee and/or manage repair and maintenance work assignments performed by previously approved 3rd party vendors and contractors performing building maintenance, equipment 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.

- Obtain, review, and negotiate price quotes from vendors for new equipment, parts, services, preventive maintenance and labor.
- Forge and maintain vendor relationships and train vendors on work order, billing procedures and relevant documentation of service, as described in applicable regulations.
- Assist upper management with demonstrating facility capabilities to new and prospective customers
- Assist VP, Manufacturing in determining whether the facility has the ability to support new or specialized client and project-specific equipment (e.g. size, environmental temperature/humidity range, power requirements, and other utilities) and manufacturing activities.
- 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 systems. Author new SOPs and initiate necessary SOP revisions as it becomes necessary.
- 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.
- Support materials management program, and assure minimums and maximums for all items in the inventory are established and maintained at all times.
- With the support of company IT team, automate systems to include, but not limited to materials management, asset management, and facility management.
- Design effective budget models for the cGMP Facility and analyze financial information (e.g. revenues, expenditures, etc) to ensure all operations are within budget. Present annual budgets to the leadership team.

Requirements

- High school diploma required. Associates degree or Bachelor's degree with focus on business, engineering, technical or management areas is preferred.
- Demonstrated proficiency with PC and/or PDA systems for work order system, email, and training.
- Expertise and track record in facilities management under GMP regulatory compliance.
- Familiarity with common GMP manufacturing and laboratory equipment, and practices.
- Experience with managing GMP projects, working with biotech manufacturing equipment, as well as equipment maintenance, and calibration.
- Skilled at negotiating contracts and managing the support services provided by external contractors.
- Fluent in English with strong communication (both written and verbal) and interpersonal skills.
- Demonstrated effectiveness in the ability to ensure quality service with business partners and customers.
- Demonstrated people management skills.

- Ability to:
  - Quickly identify and address inefficiencies or malfunctions in facility and equipment performance.
  - Manage challenging situations and recommend effective solutions to problems.
  - Effectively manage multiple tasks.
  - Effectively collaborate with internal and external teams, executive management, and clients.
  - Effectively communicate facility capabilities to prospective clients and develop valued relationships with current clients.

- Comfortable with working in a true start-up environment.
- Ability to work flexible hours to meet business and/or customer needs.
- Maintain honesty, integrity and an excellent work ethic.
- Excellent interpersonal, organizational, communication and listening skills.

Employment Type

- Full-time

Qualified applicants should send cover letter and resume to 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.