Sr. Quality Assurance Specialist, Donor Eligibility

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 Senior Quality Assurance Specialist, Donor Eligibility to facilitate our tissue supply chain operations by verifying donor eligibility and maintaining required donor documentation. This role will be responsible for overseeing blood and tissue collection operations to ensure compliance with established procedures, standards, and regulations. The Sr. QA Specialist will partner with functional groups as the point of contact for specific quality issues associated with donor operations and fosters continuous improvement of tissue supply chain operations.

Primary Responsibilities

- Serves as the primary QA point of contact for all donor and collection quality-related issues.
- Verifies and documents donor eligibility and approval to participate in blood and tissue donation programs.
- Works cross-functionally to ensure the timely release of tissue-related products.
- Approves and issues conditional and final C of A in support of product release.
- Monitors donor engagement activities and tissue collection operations to ensure compliance with internal procedures and applicable regulations.
- Performs timely reviews of donor charts, informed consents, donor history questionnaires, and related donor documentation.
- Interacts with Medical Director on donor history questionnaires, and related donor documentation eligibility questions as applicable.
- Reviews and approves donor deferral documentation.
- Manages donor enrollment databases and tracks donor participation.
- Writes, revises, and implements regulatory-compliant quality policies and procedures.
- Facilitates internal audits of tissue supply chain operations.
- Conducts and documents deviations and investigations, as needed, and ensures successful completion of associated CAPAs.
- Assists in the development of material specifications, ensures material CoA/CoC documentations is available, and performs release of incoming raw materials.

- Ensures new and existing physicians are appropriately onboarded and all required documentation is on file and current.
- Manages and maintains donation program documentation.
- Prepares annual donor reports for submission to IRB.

Requirements

- Bachelor's degree in science or equivalent industry experience with 5 + years of experience working in a GxP environment or other regulated industry.
- Prior experience in a donor-focused quality role, strongly preferred.
- Experience with apheresis, whole blood, placenta, umbilical cord- and cord blood-derived products is preferred.
- Familiarity with cGTP and cGMP requirements, specifically 21CFR 606, 630 and 1271, as well as AABB and AATB requirements.
- Experience supporting internal, regulatory, and partner audits is preferred.
- Familiarity with electronic documentation systems a plus.
- Adept at Microsoft Office, including Word, Excel, PowerPoint, Outlook.
- Comfortable with working in a true fast-paced and dynamic 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

Applicants should send cover letter and resume to Ms. Danielle Smyla (danielle@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.