

Director, Analytical Development

The Company:

OrganaBio is a Miami-based biotechnology company, supplying primary cells, cell-derived products (conditioned media and exosomes), and GMP manufacturing solutions to the regenerative medicine industry. OrganaBio's vision is to transform a world of cell and gene research to a world of cell and gene therapies. We cater to the market segments that the major suppliers ignore. At OrganaBio, we empower our customers' people, processes, and products on their journey to commercialization.

The Role:

OrganaBio is seeking a Director of Analytical Development to oversee method establishment and transfer to the Analytical Testing Services function at our Miami, FL GMP facility.

As leader of the analytical development department, you will be overseeing the design, development, execution, and transfer of bioassays to facilitate manufacturing and testing of various gene therapy and cell therapy products.

You will have a significant role in customer relationships, growing talent, and building trust with our partners as we establish our GMP manufacturing and analytical testing site.

Primary Job Responsibilities:

- Own Bioassay development and execution of novel product characterization test methods.
- Define science-driven, phase appropriate, and risk-based analytical development strategies to support the internal and external projects at advancing clinical development stages.
- Provides strong knowledge, mentorship, and technical leadership of analytical development processes to train junior staff and build in-house analytical development training capabilities.
- Ensure methods are developed in accordance with ICH guidance documents, including management of associated deliverables and timelines.
- Support quality control technical investigations, OOS, OOTs and release assay troubleshooting.
- Lead implementation of systems to manage sample receipt, test execution, and reporting.
- Primary Subject Matter Expert in support of regulatory filings and inspections.
- Other duties as defined within the scope of the position.

Primary Job Requirements:

- A track record with analytical development and method qualification supporting early and/or late-stage Cell therapy, Gene therapy, LNP, Exosome, and/or mRNA products.
- Thorough knowledge of cGMP guidelines, specifically GDP and Data Integrity requirements.
- Relevant technical proficiencies in primary cell culture, flow cytometry, qPCR, ELISA, westerns, molecular biology methods, etc.
- Demonstrated management of a relevant laboratory function is required.
- Expert communication skills to translate technical concepts and comprehensive data analysis summaries to build relationships with key stakeholders.
- Experience supporting internal regulatory and partner inspections is preferred.
- Experience with technical writing for analytical sections of NDAs, MAAs is preferred.
- Ability to work in a fast-paced and dynamic startup environment.



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.

Qualified applicants are welcome to apply.
Send CV or resume to careers@organabio.com.