



Senior Bioprocess Scientist

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 an experienced Senior Bioprocess Scientist to collaborate with cross-functional teams, to participate in the development and production of novel research use and cGMP grade cell and cell-based materials for cell therapies. This position will ensure that products will be developed and manufactured under GLP and GMP practices, will participate in tech transfer from Process and Product Development (PPD) to Manufacturing and customers, and will support the Manufacturing program and Business Development team with technical support.

Primary Responsibilities

- Deliver on scientific goals in support of corporate objectives, under the direction of the Management Team
- Lead the development and optimization of robust and scalable processes for product manufacture (including multiple adherent and non-adherent cell types), using 3D bioreactors of various scale, progressing from research- to commercial-scale bioreactors
- Lead the development and characterization of novel products that include extracellular vesicles, using translation-ready and scalable production systems
- Contribute to the development of new, custom, or existing products, with reasonable cost of goods, and according to established project timelines
- Contribute to Scopes of Work and project execution for OrganaBio Partner Programs
- Work independently and with a level of functional expertise necessary to influence and execute product technical development
- Participate in the design and lead the assessment of critical process parameters and process / product characterization utilizing methods that include, but are not limited to, FLOW analysis, ELISA and ELISA-based methods, multi-plex assays, histological assays, etc
- Collaborate with Quality Control to establish appropriate critical to quality (CTQ) metrics and validated assessment methods
- Analyze accumulated data to streamline process/product development and consistently report out to Management Team
- Write and review technical reports and Standard Operating Procedures
- Manage technology transfer from PPD to Manufacturing and lead Manufacturing in troubleshooting production issues with standard and specialized products



- Serve as a Subject Matter Expert and liaison to Process Development, Manufacturing Science and Technology (MSAT), Manufacturing, and Business Development
- Supervise/coach scientists and cell processing specialists and help manage routine team operations
- Work closely with other functional teams in a matrix organization to move projects forward
- Provide regular production status updates to PD, MSAT, and Manufacturing teams
- Support external audits and inspections, as required
- Support daily laboratory operations, including cleaning, maintenance, ordering, and inventory management

Requirements

- M.S. in an applicable field (Bioengineering, Chemical Engineering, Biological or relevant process related sciences) with 5+ years of experience, or 7+ experience in an applicable field
- Extensive cell culture experience required
- Minimum 5 years of experience in process development and/or GLP/GMP manufacturing of cell and gene therapy products
- Basic understanding of cell biology, immunology, bioprocess and engineering principles
- 2 years of experience with primary cell isolation and aseptic techniques.
 - Experience with birth tissue-derived cells (MSCs, HSCs, immune cells) a plus
 - Experience in a GLP and/or GMP manufacturing setting a plus
- Well-honed analytical skills and knowledge of statistical software to conduct data analysis
- Strong experience in upstream and downstream cell processing and culture technologies in support of the finished materials production
- Bioreactor process development experience a plus
- Ability to apply scientific and engineering approaches to problem solving and process development
- Experience in process optimization, process characterization, process and product validation, equipment validation and SOP authoring
- Robust oral and written communication skills.
- Outstanding interpersonal and conflict resolution skills.
- Extreme attention to detail and thorough record-keeping
- Ability to quantify experimental results and relay findings to internal and external teams
- Excellent organizational and time-management skills, and ability to manage multiple concurrent projects
- Ability to work independently and collaboratively in a fast-paced, dynamic environment
- Productive, solution-oriented work ethic
- Weekend and late hours required at times
- Flexible Mindset – This position will initially report into PD, but responsibilities and position within the organization will evolve as the organization grows



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.