OrganaBio

The Company:

OrganaBio is a Miami-based company that will supplies tissues, 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 research to a world of cell therapies. We cater to the market segments that the major suppliers ignore. At OrganaBio, we empower our customers' people, process and products on their journey to commercialization. OrganaBio has closed a Series A financing round and is assembling a team of established, highly-motivated individuals who can thrive in a fast-paced small business environment.

The Role:

OrganaBio is seeking an experienced Associate Director of Process Development to lead and collaborate with cross-functional teams to oversee the development and production of novel research grade and clinical materials for cell therapies. This Director level hire will ensure products will be developed under GLP and GMP practices, will oversee tech transfer from Development to the Manufacturing group/customers and will support Manufacturing and customers with technical support.

Primary Job Responsibilities:

- Lead Product Development Team to develop and optimize robust and scalable processes for product manufacturing
    - Knowledge of 2D and 3D culture process and vertical wheel bioreactors is preferred
- Develop robust designs for new, custom, and/or existing products that can be produced cost-effectively and according to established project timelines
    - Generate Bill of Materials and Cost of Goods for products
    - Manage budgeting and forecasting for the department
- Supervise/coach scientists and manage routine team operations
- Define and manage timelines and deliverables of manufacturing processes to meet corporate and customer timelines
- Generate Scopes of Work & budgets for custom products along with Business Development team
    - Generate Master Project Plans, execute to timelines, and deliver product to customers
- Work independently and with a level of functional expertise necessary to influence and execute technical and project delivery
- Design and lead assessment of critical process parameters, and process and product characterization
    - Work closely with Quality Control on analytical assay development and tech transfer
- Collaborate with Quality Control and Quality Assurance to establish appropriate critical to quality (CTQ) metrics
- Write, review, and approve experimental protocols, SOPs, MBRs, technical reports, etc.
- Lead and manage technology transfer to Manufacturing. Assist Manufacturing in troubleshooting production issues on standard and custom products.
- Work closely with other functional teams in a matrix organization to move projects forward
- Provide regular production status updates to Executive Management
- Support regulatory filings and inspections (FDA and other applicable regulatory agencies) as required
- Serve as an SME (Subject Matter Expert) and liaison to senior management, cross-functional areas and external organizations
- Build and manage a high performing Process Development Team through hiring, training, supervision, mentoring and reviewing of key personnel
- Provide support towards the implementation and validation of electronic systems related to inventory and budget management, document management, electronic batch records, etc

Primary Job Requirements:

- PhD in an applicable field (Bioengineering, Chemical Engineering, Biological or relevant process related sciences), with 10+ years of industry experience
- Extensive cell culture experience required
- Minimal 5 years of industry experience in process development and/or GLP/GMP manufacturing of cell therapy products
- Strong experience in upstream and downstream cell processing and culture technologies for clinical materials production
- Demonstration of knowledge of industry needs and trends
- Ability to apply scientific and engineering approaches to problem solving and process development
- Ability to introduce new technologies to improve and accelerate manufacturing process
- Extensive experience in process optimization, risk assessment, product and process characterization, validation, data analysis and SOP authoring
- Strong verbal and written communication skills, ability to manage multiple projects simultaneously and attention to details, highly organized and self-motivated
- Management level experience in an industry process development environment is required

Qualified applicants should send CV or resume to Dr. Elina Linetsky at 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.