The Company:

OrganaBio is a thriving startup company that aims to support the life sciences community. Based in Miami, OrganaBio's vision is to transform a world of cell and gene research to a world of cell and gene therapies. Our proprietary supply chain provides its customers with mission-critical resources, from birth tissue-derived progenitor and immune cells to a suite of expert services and flexible cGMP manufacturing solutions. This enhances our customers' success in clinical translation and commercialization. Our products include placenta-, umbilical cord- and cord blood-derived MSCs, HSCs, NK cells, T cells, B cells and others. In addition, we are democratizing access to cGMP manufacturing space to provide a complete solution from cell sourcing through clinical manufacturing for our customers. 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 startup environment.

The Role:

OrganaBio is looking for an experienced individual to lead site operations for the company's new cell and gene therapy cGMP manufacturing facility in the Miami Florida area. The head of GMP Operations is responsible for the overall operational management of the Good Manufacturing Practices (GMP) and Clinical Manufacturing Facility. Working in close collaboration with the Scientific Directors specific to product lines (e.g., MSCs, immune cells, exosomes, viral vectors, etc), this individual will oversee all day-to-day GMP operations, including project and timeline management, budget, personnel, facility management, and Quality Control. This individual is responsible for ensuring that GMP manufacturing operations delivers all products in a timely, compliant, and fiscally responsible fashion. The head of GMP Operations will also be responsible for long term facility capacity planning, building space planning, construction project management, layout and outfitting, and management of maintenance and support operations. This role will report directly to the Chief Executive Officer.

Primary Job Responsibilities:

- Works with external vendors, contractors and project managers to deliver the on time and on budget construction and commissioning of the company's new GMP manufacturing facility located in the Miami Florida area.
- Works with the company's other departments to recruit appropriate staff and build the required operational infrastructure to develop, manufacture and deliver the company's cell-based products and to support customer manufacturing operations in a multi-tenant GMP facility.
- Works with Corporate and Business Development to contract customers and deliver a positive manufacturing experience.
- Directs the day-to-day operations of the GMP facility and all associated activities through both hands-on activities and supervision of GMP staff.
- Directs operations to ensure compliance with applicable federal, state and city regulations for product manufacture and distribution, environmental, health & safety and company policies and procedures.
- Oversees all GMP resources, including Technicians, facilities, and Quality Control, to support company and client production goals.
- Is responsible for sound project and financial management of the facility and operations, including preparation of and adherence to budgets, timelines, and standards.

- Plays strategic role in estimating future capacity, serving as primary liaison with suppliers and purchasing staff.
- Manages and drives all operation related functions to optimize GMP efficiency.
- Supervises and assists in daily operational activities related to the GMP manufacturing of cell and gene therapy products.
- Ensures that appropriate and accurate documentation surrounding GMP activities supporting product quality is maintained.
- Provides internal and external sponsors and collaborators with timely production status reports.
- Facilitates problem-solving, contingency planning, and decision-making for the Miami Option C facility and work collaboratively with other functional teams.
- Assists in negotiating contracts and supply agreements.

Qualifications and Skills:

- Advanced degree in Biomedical Engineering, Chemical Engineering, Cellular or Molecular Biology or related field with 10+ years of industry experience. Title and compensation to be commensurate with experience.
- Thorough knowledge of Good Manufacturing Practices and US FDA regulations is a must.
- Experience with tech transfer from process development into cGMP manufacturing is a must.
- Experience in cGMP manufacturing of cell and/or gene therapy products is a must.
- Proven ability in bioprocess development to improve and refine scalable production processes in a GMP environment.
- Minimum of 3 years of experience in bioprocess engineering or bioprocessing.
- Must have the ability to apply solid scientific methodology to problem solving.
- Must have knowledge and understanding of robust, reproducible and scalable manufacturing processes and platforms.
- Must have proven experience of the design, construction, commissioning and operation of facilities for the commercial manufacture of cell and gene therapy products.
- Solid understanding of a cell/gene therapy product development lifecycle from pre-clinical development through to commercial manufacturing.
- Ability to make decisions that prioritize quality while with a sense of urgency in time-constrained scenarios.
- Demonstrated ability to manage a team.
- Strong verbal and written communication skills.
- Accountable and personally responsible (individually and as part of a team) to the organization's success.

Qualified applicants should send CV or resume to careers@organabio.com.