Interested Parties should contact:
Keith Ryan kryan@geneousbiomedical.com
508 359 4120

Position	**Senior Director, Process Development**
Location	**Miami, FL**
Reports to:	**VP, Operations**

POSITION SUMMARY:

As a member of the Operations management team, the Senior Director of Process Engineering is responsible for managing scale-up, production optimization and establishment of manufacturing systems capable of supporting commercial volumes and quality levels. Products commercially available or in the pipeline include medical devices, tissue products and biologics. This includes captive manufacturing, as well as internally developed products developed and those produced by third party partners. While the primary focus is to deliver concepts from R&D into feasible manufacturing options and on the introduction of new products, this person is also responsible for the continuous operational improvement of existing products.

The Senior Director of Process Development works closely with R&D teams to guide the development of product innovations so that they can be manufactured in an efficient manner and meet all quality, regulatory and volume requirements. He or she manages a team of highly skilled, multi-disciplined engineers and scientists that begin with R&D concepts and may carry them through facility design, process modeling, scale-up, technical transfer and ongoing manufacturing technical support. Additionally, this position works closely with R&D teams to assure newly created products can be manufactured in a consistent manner using validated processes.

The Senior Director of Process Development defines and manages multiple concurrent projects that are essential to the future success of the company. The incumbent has considerable experience launching and optimizing GMP regulated products and is familiar with the collaborative roles played by R&D, Quality, Facilities and Finance. He/She works to align technical transfer and process optimization activities with overall company goals, and assures that their teams are aligned to deliver those objectives. The incumbent will play a major role in defining the culture within the Operations organization and will deliver an environment that emphasizes critical thinking, clear and concise communication, a bias toward action, and an emphasis on trust and respect.

DUTIES AND RESPONSIBILITIES:

1. Directs team members and individual contributors in support of Development, Tech Transfer, and Facility planning operations. Develops and maintains engineering systems, standards, and procedures to deliver concepts from R&D into feasible manufacturing options. Creates and maintains facility and process modeling that identifies capabilities and predicts facility investments. Develops, communicates, and implements strategic goals in support of Manufacturing operations and Facility utilization.
2. Provides recommendations and guidance regarding equipment, consumables and software used for early stage development projects to avoid potential downstream scale up issues.

3. Directs team members and individual contributors in support of internal and external Manufacturing operations. Provides in depth process engineering support for critical manufacturing operations. Leads team of Process System Owners, responsible for execution of and adherence to engineering and operational design standards.
4. Develops and maintains project plans.
5. Develops people and leaders within the organization. Defines personal development plans and conducts talent/capability reviews. Maintains/creates Process Development operations that support current business activities.
6. Manage activities in compliance with current Good Manufacturing Practice (cGMP) and other applicable regulations.
7. Provide leadership in the preparation of annual operating and capital budgets. Provide appropriate documentation to justify intended expenditures and expected returns.
8. Manage the agreed upon financial budgets and develop containment or corrective actions to address excursions from plan.
9. Provide Person-In-Plant (PIP) support when necessary.
10. Successfully resolve all Non-Conforming Reports (NCR) and Corrective and Preventative Actions (CAPA) in a prompt manner.
11. Represent company at both internal and external functions. Will require occasional presentations to a variety of audiences.

CHARACTERISTIC TASKS AND THEIR FREQUENCIES:

% Approximate Time	Description
70%	Oversee GMP/GTP operational functions.
20%	Work with Product Development, Quality, Customer Support and Finance teams.
10%	Other duties as assigned

POSITION EXPERTISE/QUALIFICATIONS:

- A minimum of ten (15) years' experience in Process Engineering in Biotech or Pharma industry including five (10) years of supervisory/management experience. Experience with upstream and downstream processing is essential.
- Knowledge of process design, facility design, GMP operations, utilities systems and current pharmaceutical practices is essential. Excellent leadership, project management, organizational, communication, and inter-personal skills are required.

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- Provide subject matter expertise regarding Process Equipment, Distributed Control Systems, Equipment/System Validation, Facility Operations, Instrumentation and Biotech and Pharma Manufacturing Unit Operations.
- Thorough understanding of GTP, cGMPs, quality systems and compliance requirements. Experience with BLA highly valued.
- Demonstrated strategic perspective with good decision-making quality in a highly complex environment.
- Ability to address obstacles with energy and determination, and exhibit commitment to change and passion for best interests.
- Demonstrated ability to recruit and grow talent.
- Experience bringing new products from development to full commercialization.
- Strong leadership skills to engage, influence and motivate colleagues as well as subordinates in the organization. Ability to manage up as well as down organizations.
- Bachelor's Degree or equivalent, preferably in a hard science or engineering discipline. Master's degree in business or technology desired.
- Minimum 15 years of experience in GMP/GTP environment and experience working with the US Food and Drug Administration. Demonstrated experience interfacing with auditors and regulators.
- Experience in designing and overseeing construction of GMP/GTP manufacturing facilities.
- Strong writing, verbal and communication skills. Ability to prepare and deliver PowerPoint or similar presentations to a variety of audiences.