Director of Manufacturing Engineering

About MaxCyte:

MaxCyte is a leading commercial cell-engineering company focused on providing enabling platform technologies to advance innovative cell-based research as well as next-generation cell therapeutic discovery, development, and commercialization. Over the past 20 years, we have developed and commercialized our proprietary Flow Electroporation® platform, which facilitates complex engineering of a wide variety of cells. Our ExPERT™ platform, which is based on our Flow Electroporation technology, has been designed to support the rapidly expanding cell therapy market and can be utilized across the continuum of the high-growth cell therapy sector, from discovery and development through commercialization of next-generation, cell-based medicines. The ExPERT family of products includes: four instruments, the ATx™, STx™, GTx™, and VLx™; a portfolio of proprietary related processing assemblies or disposables; and software protocols, all supported by a robust worldwide intellectual property portfolio.

Job Summary:

The Director of Manufacturing Engineering manages all Instrumentation and Process Assembly (PA) manufacturing engineering activities. Directs and coordinates manufacturing projects and staff to support on-going continuous improvements and new product development projects/programs.

Job Duties:

- Manage high performing team to deliver quality results and meet the needs of MaxCyte's internal and external customers.
- Responsible for Manufacturing Engineering department projects, staff, and budget, including machine shop activity and safety.
- Oversee the development of assembly processes that can be validated for repeatability and reproducibility.
- Supervise direct reports daily activities, reward and recognize for above and beyond work and discipline when required per MaxCyte's policies.
- Responsible for technical transfer to contract manufacturers and others.

- Responsible for capacity planning i.e., all tooling and equipment that supports production.
- Responsible for vertically integrating critical manufacturing process as needed.
- Participate in troubleshooting Instrument, PA's and assembly equipment. Respond and correct manufacturing related field issues expeditiously.
- Participate in product development process including design for manufacturing, assembly techniques, implementation of automation, and IQ/OQ/PQ qualifications.
- Promote and implement Six Sigma (DMAIC) methodology to achieve company quality, delivery and cost goals.
- Develop manufacturing processes that meet 1.33 Cpk or greater.
- Support and drive a continuous improvement culture.
- Participate and development of inspection, calibration, integration, verification, and validations for Instruments and Process Assemblies (PA). Implement product safety testing per regulations (e.g., UL, IEC, TUV) and EMI/EMC standards if required.
- Oversees general preventative maintenance of assembly automation, fixtures, and jigs to ensure all manufacturing systems meet performance specifications and criterion.
- Provides manufacturing project oversight to ensure the projects are meeting milestones and budget requirements. Manage project activity to resolve all issue to keep projects on track.
- Communicates with vendors, suppliers, contractors, and others involved in procurement, of production equipment.
- Complies and adheres to all Company health, safety and environmental policies.

Job Requirements:

- B.S. in Mechanical, Electrical or Biomedical Engineering and 10+ years of relevant experience, MS preferred.
- Project management certification/training is a plus.
- 5+ years supervisory experience
- Experience working in a regulated business such as medical device or Biotech industry is preferred.

- Must be a hands-on manager with a full understanding of the assembly process development including experience: a) developing assembly processes and implementing controls, b) in machining techniques and materials, and c) assembly techniques such as pressing, fasteners, ultrasonic welding, RF welding, injection molding, UV adhesives, electronic instrument testing, HI Pot testing, etc.
- Ability to design mechanisms using solid modeling software.
- Experience with SolidWorks and AutoCAD to create complete documentation packages.
- Experience in identifying critical to quality dimensions, and other criteria to ensure all production products meet the functional requirements.
- Familiar with international quality and safety regulations including cGMP, ISO 9000, ISO 13485, IEC 61010 and IEC 60601-1.
- Proven track record on the ability to lead project teams in new product technology transfer activities.
- Strong oral and written communication skills.
- Strong organization and time management skills.
- Ability to travel 10-15 percent.

Leadership Competencies:

- Action Oriented – Ability to take on new opportunities and tough challenges with a sense of urgency, high energy, and enthusiasm. Readily takes action on challenges, without unnecessary planning. Identifies and seizes new opportunities. Displays a can-do attitude in good and bad times. Steps up to handle tough issues.
- Collaborates – Builds partnerships and works collaboratively with others to meet shared objectives. Represents own interests while being fair to others and their areas. Partners with others to get work done. Credits others for their contributions and accomplishments. Gains trust and support of others.
- Decision Quality – Makes good and timely decisions that keep the organization moving forward. Makes sound decisions, even in the absence of complete information. Relies on a mixture of analysis, wisdom, experience, and judgment when making decisions. Considers all relevant factors and uses appropriate decision-making criteria and principles. Recognizes when a quick 80% solution will suffice.
- Drives Results – Consistently achieves results, even under tough circumstances. Has a strong bottom-line orientation. Persists in accomplishing objectives despite obstacles

and setbacks. Has a track record of exceeding goals successfully. Pushes self and helps others achieve results.

- Ensures Accountability – Holds self and others accountable to meet commitments. Acts with a clear sense of ownership. Takes personal responsibility for decisions, actions, and failures. Establishes clear responsibilities and processes for monitoring work and measuring results. Designs feedback loops into work.
- Instills Trust – Gains the confidence and trust of others through honesty, integrity and authenticity. Follows through on commitments. Is seen as direct and truthful. Keeps confidences. Practices what he/she preaches. Shows consistency between words and actions.

MaxCyte, Inc. is an equal opportunity employer. To apply, please send your resume and cover letter to careers@maxcyte.com. Please reference ***Director of Manufacturing Engineering*** in the subject line.