



## Senior Mechanical Engineer

### **About MaxCyte:**

MaxCyte is a leading provider of cell-engineering platform technologies to advance innovative cell-based research, development, and commercialization of next-generation cell therapies. The company's existing customer base ranges from large biopharmaceutical companies — including 20 of the top 25 pharmaceutical companies based on 2020 global revenue — to hundreds of biotechnology companies and academic translational research centers. MaxCyte has granted 14 strategic platform licenses to commercial cell therapy developers that allow for more than 75 clinical programs. Founded in 1998, MaxCyte is headquartered in Gaithersburg, Maryland, US.

### **Job Summary:**

The Senior Design Engineer researches, plans, designs, develops and validates life science Instrumentation, Disposables, and assembly processes and equipment. The Senior Design Engineer generates and implements ideas/concepts for new products and is involved in every aspect of instrumentation and disposable development and manufacture to meet the needs of customers, scientists, and clinical partners.

### **Job Responsibilities:**

- Responsible for all aspects of product development including: product definition, technical specification, documentation, product design, product manufacturing integration, and qualification/validation.
- Reviews design information and specifications to determine critical to quality parameters of design.
- Designs for manufacturing (DFM). Develops products considering maximum variation needed to mass produce using manufacturing automation.
- Statistically analyze variable and attribute data to support process development and validations (PQ)
- Develops assembly processes for disposables that are flexible and can be scaled to meet high annual volumes and high mix disposable product lines.

- Creates product development documentation to support the design controls stage gate process and meet GMP requirements.
- Works with R&D to evaluate product prototypes, performance, and design features.
- Conceptualizes novel configurations for products.
- Supports lifecycle of Engineering Change Controls.
- Ensures development efforts for products are effectively transferred to manufacturing.
- Works with suppliers with respect to specifications and fabrication and purchasing components and subsystems.
- Supports, as needed, technical investigations pertaining to MaxCyte products.
- Applies design and manufacturing strategies to meet project objectives and ensures design outputs meet requirements.
- Oversees development activities of outsourced vendors
- Project manages, creates, and maintains Gantt charts. Leads project meetings and publishes meeting minutes.
- Creates mechanical drawings for fabrication of mechanical components.
- Establishes and maintains engineering standards and procedures.
- Complies and adheres to all Company health, safety and environmental policies.
- Other duties as assigned.

**Job Requirements:**

- B.S. in Mechanical or Biomedical Engineering and 5 - 8 years of experience designing prototypes and products for manufacture; or equivalent. MSME Preferred
- Instrument and disposables design experience in life sciences or medical device industries preferred.
- Six Sigma Black Belt certified (DMAIC) with 2-5 years working experience in an R&D and manufacturing environment
- Demonstrated experience in the product development process, from design conception through final approval. Disposable design and assembly process development experience highly desirable.
- Solid understanding of mechanical design principles and the ability to independently perform complex problem solving.
- Hands on experience with design control and change control.

- Proficient with CAD software (Solidworks, AutoCAD).
- Demonstrated project management experience. Formal PMP trained desired.
- Familiar with international quality and safety regulations including cGMP, ISO9001, and/or IEC 60601-1 and 61010
- Strong oral and written communication skills.
- Strong organization and time management skills
- Ability to work effectively in team environment as well individually.
- Demonstrated ability to be creative and willing to contribute to areas outside of personal expertise.
- Ability to travel 10-15 %

MaxCyte, Inc. is an equal opportunity employer. To apply, please send your resume and cover letter to [careers@maxcyte.com](mailto:careers@maxcyte.com). Please reference **Mechanical Engineer** in the subject line.