Quality Engineer- Life Sciences Instrument Systems

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 15 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 Quality Engineer provides operational support related to field/customer issues, instrument verification, manufacturing, troubleshooting, manufacturing test design, and technical maintenance of instrumentation and software. Works independently. This individual reports to the Senior Director of Quality and Regulatory.

Job Responsibilities:

- Conducts all activities in compliance with Standard Operating Procedures and Manufacturing Batch Records outlined in MaxCyte's Quality Management System.
- Interacts with external collaborators and/or customers from time-to-time and may need to travel.
- Drafts and reviews procedures and work instructions for manufacturing and operations processes.
- Provides operational support and monitors assembly process control. Evaluates and recommends process improvements utilizing LEAN principles.
- Provides technical support to facilitate quality investigations, root cause analysis and corrective action/preventive action (CAPA) implementation.
- Initiates engineering change requests as functional change owner and oversees the execution and implementation of proposed changes.

- Supports internal and external audits and quality system certification
- Supports ongoing product enhancement activities
- Assists with other design and/or development activities.
- Complies with all applicable policies regarding health, safety, and environmental policies.
- Other responsibilities as assigned

Job Qualifications:

- B.S. / M.S. in Mechanical, Instrumentation, Biomedical or Electrical Engineering or other related discipline with at least 2-5 years of hands-on assembly and testing of instrumentation systems specific to medical devices and/or laboratory equipment; or 10+ years of relevant work experience.
- Prior experience with software development / programming for customization of user interface is desirable.
- Demonstrated computer skills; experience using MS Office [Word, Excel, PowerPoint]
- Able to troubleshoot mechanical and electrical components
- Customer oriented. Resolves customer problems and issues through technical expertise and troubleshooting
- Familiarity with manufacturing processes and design control
- Prior experience with LEAN manufacturing principles and is highly desirable
- Working knowledge of QSR, GMP, and ISO requirements
- Team-oriented individual with strong verbal, written and interpersonal skills
- Has a "do what it takes" attitude to meet customer deadlines
- Approximately 10% travel

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