QC and Analytical Development Manager

ABOUT MAXCYTE:
MaxCyte is a global cell-based medicines and life sciences company applying its patented cell engineering technology to help patients with high unmet medical needs in a broad range of conditions. MaxCyte is developing novel CARMA therapies for its own pipeline. CARMA is MaxCyte’s mRNA-based proprietary platform for autologous cell therapy. In addition, through its core business, the Company leverages its Flow Electroporation® Technology to enable its partners across the biopharmaceutical industry to advance the development of innovative medicines, particularly in cell therapy, including gene editing and immuno-oncology. The Company has placed its cutting-edge flow electroporation instruments worldwide, including with nine of the top 10 global biopharmaceutical companies, and has more than 55 partnered program licenses in cell therapy including more than 25 licensed for clinical use. With its robust delivery technology, MaxCyte helps its partners to unlock the full potential of their products.

Founded in 1999, MaxCyte is based in Gaithersburg, Maryland.

Job Summary:
The primary focus of the QC and Analytical Development Manager is to oversee the Quality Control (QC) operations at the Contract Development and Manufacturing Organization (CDMO) in support of product testing and release. In addition, this individual will provide technical expertise and oversee, as needed, method development and optimization as well as method transfer to and from CDMO, collaborators and partners to ensure robust analytical method GMP and ICH compliance are maintained. We are seeking a demonstrated leader with the breadth of professional experience and drive to work effectively with both internal and external partners in a highly matrixed and cross-functional organization with a tactical focus on meeting the scientific, clinical, analytical and business requirements of the department in line with company goals.
Job Duties:

- Oversight of CDMO QC operations to support MaxCyte’s Phase I Clinical Study
  - Review and approve QC data from cGMP manufacturing campaign for lot disposition
  - Perform technical QC review and support QC nonconformance or Out-Of-Specification (OOS) investigations
  - Provide QC/Analytical training
  - Assist with CAPA implementation and change control activities
  - Manage stability studies/program

- Execute assay/analytical method development projects to support current clinical study as well as future pipeline

- Provided as needed MSAT support

- Assist with CAPA implementation and Change Control activities at MaxCyte, CDMO or Contract Testing Laboratory

- Provide lab oversight and management of MaxCyte’s internal PD/Analytical Development Lab

- Support activities related to the transfer, qualification and validation of analytical methods

- Develop, revise and review SOPs, protocols and technical reports

- Evaluate analytical instrumentation to support ongoing analytical method development initiatives

- Evaluate back up contract testing laboratories

- Provide as needed support and contributions to IND filing/regulatory submission as well as audit or inspection support as the technical SME

- Complies with all applicable policies regarding health, safety, and environmental policies

- Others
Job Requirements:

- Bachelor's degree in Life Sciences or closely related discipline with a strong background in biology/immunology
- 5+ years of experience working in cell/gene therapy or biopharmaceutical industry
- Experienced working and managing CDMO and Contract Testing Laboratory
- Extensive industry experience with externally-facing roles with relevant hands on experience in analytical techniques, including but not limited to, Flow Cytometry, Real Time PCR, ELISA, Cell Viability measurement, etc.
- Experience in performing analytical method development, qualification, validation and support method transfer activities
- Familiarity with FDA, ICH and cGMP guidelines
- Thorough understanding of cutting-edge analytical tools and technologies
- Strong quantitative and qualitative analytical abilities
- Ability to think critically and demonstrate troubleshooting/problem solving skills.
- Self-motivated with a strong sense of ownership in areas of responsibility
- Excellent organization, time and project management skills. Ability to multitask, prioritize work and adapt in a constantly evolving, fast-pace environment with minimal supervision
- High energy level and a positive outlook coupled with the requisite “can do” attitude. Willingness to do what it takes to achieve organizational goals and overcome obstacles
- Excellent interpersonal, verbal and written communication skills including the ability to initiate and contribute to discussions and build strong relationships are essential in this highly collaborative and matrixed work environment
- Demonstrated computer skills; experience using MS Office and other data analysis software and other related applications

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