Medical Director, Clinical Development (Oncology)

About MaxCyte:
MaxCyte is a global clinical-stage cell-based therapies and life sciences company applying its proprietary cell engineering platform to deliver the advances of cell-based therapy to patients with high unmet medical needs. MaxCyte is developing novel CARMA(TM) therapies for its own pipeline, with its first drug candidate in a Phase I clinical trial. CARMA is MaxCyte’s mRNA-based proprietary therapeutic platform for autologous cell therapy for the treatment of solid cancers. In addition, through its life sciences business, MaxCyte leverages its Flow Electroporation(R) Technology to enable its biopharmaceutical partners to advance the development of innovative medicines, particularly in cell therapy. MaxCyte has placed its flow electroporation instruments worldwide, with all of the top ten global biopharmaceutical companies. The Company now has more than 70 partnered program licenses in cell therapy with more than 35 licensed for clinical use, including four announced commercial licenses covering potentially more than 30 products. With its robust delivery technology platform, MaxCyte helps its partners to unlock the full potential of their products. For more information, visit www.maxcyte.com.

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

Job Summary:
The Medical Director/Sr. Medical Director, Clinical Development (Oncology) will play a key role in the development of products from its CARMA platform, its first being MCY-M11, a chimeric antigen receptor drug candidate. The successful candidate will provide medical and scientific expertise on the strategy, design, execution and interpretation of clinical stage programs relating to the treatment of solid or hematologic cancers using MaxCyte’s CARMA therapeutic platform. The position will report to the Chief Medical Officer.

The Medical Director/Sr. Medical Director is responsible for the day to day clinical trial activities and for ensuring that all studies are conducted with the highest level of ethical and safety standards and compliant with GCP and all regulatory policies. Duties include primary interactions with site investigators and CRO, functioning as the medical representative on the integrated project team and providing medical consultations as needed across studies.

Job Responsibilities:
• Serve as the medical monitor for one or more trials in early phase of development, including Phase 1 safety, dose and signal finding, and Phase 2 proof-of-concept trials.
• Contribute to the implementation of a sound clinical development strategy and implementation of operational plans for clinical trials in various malignancies.
• Review all individual adverse experience reports for accuracy and clinical importance and characterize their relationship to the study drug, severity and seriousness; work closely with regulatory and other functions to ensure appropriate compliance with FDA or other regulatory agencies.
• Review data listings, laboratory data and patient safety and efficacy data to establish the presence or absence of abnormal trends and follow up as appropriate.
• Leads clinical trial implementation, ongoing monitoring and evaluation, working closely and regularly with external investigators, Clinical Operations and others internally and externally. Assesses project progress, monitors variances and is expected to proactively identify any issues or challenges and develop, recommend and implement strategies to effectively resolve such
• Leads the preparation of clinical protocols, integrated clinical and statistical summary reports, clinical sections included in various regulatory submissions (IND, regulatory response documents, etc.) and peer-review publications for national and international meetings and/or journals.
• Present findings internally and externally (such as investigator meetings, regulatory agency meetings, medical conferences) acting as a spokesperson for MaxCyte relating to the trial/indication.
• Provide medical insight to inform program and/or project investment decisions.
• Support various meetings with external experts, advisors and business development teams.

Job Requirements:
• M.D. with board certification (or board equivalent) in medical oncology.
• At least 5 years of drug development and clinical trial experience with at least 3 years in oncology-related clinical research. Early phase development, immuno-oncology and/or cell therapy experience preferred/desirable.
• Extensive knowledge of clinical trial methodology, regulatory and compliance requirements governing clinical trials, and experience in the development of clinical strategy and the design of study protocols.
• Excellent interpersonal skills; ability to build key relationships easily across all levels of the company; ability to influence without conflict.
• Ability to effectively communicate with external audiences to present relevant program and company information (i.e. investigators, conferences)
• Able to engage and collaborate with external collaborators (i.e. industry partner)
• Capable of highly independent work as well as being a team player and role model.

Additional details
• MCY-M11 is a chimeric antigen receptor drug candidate, initially to be tested in a phase 1 study in two indications, relapsed/refractory ovarian cancer and peritoneal mesothelioma. The study is being initiated in the second half of 2018.
• Further development is planned with additional studies expected to initiate in 2019.
• Top investigators and institutions and great investigator enthusiasm

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