Manager, Process Development

About CARMA Cell Therapies:

CARMA Cell Therapies, Inc. is a wholly owned subsidiary of MaxCyte, Inc. focused on advancement of novel mRNA-based cell therapies for cancer and other diseases with serious unmet needs. MaxCyte has developed CARMA, a novel and proprietary platform for the development of non-viral, human messenger RNA (mRNA)-based, chimeric antigen receptor (CAR) or T-cell receptor (TCR) redirected immune cell therapies. CARMA [derived from CAR mRNA] utilizes MaxCyte's Flow Electroporation® technology for highly efficient, non-viral, delivery of one or more mRNA(s) into non-activated peripheral blood mononuclear cells (PBMCs) or isolated immune cells such as T- or NK-cells. CARMA offers the potential for a safer cell therapy, as a result of transient expression of receptor(s) and a non-viral delivery approach. Together, CARMA and MaxCyte's EXPERT™ family of instruments also offer the potential for a significantly streamlined, scalable, and cost-effective GMP manufacturing process without the complexity of virus-based products. At the start of 2020, MaxCyte established CARMA Cell Therapies as a wholly owned subsidiary to facilitate independent investment and new partnerships to advance the CARMA platform. The Company expects CARMA to be self-funded by 2021.

Job Summary:

The Manager, Process Development position plays a key role in developing and optimizing the clinical manufacturing processes for CARMA cell therapy products. The Process Development Manager manages relationships and deliverables from other functional groups as it applies to process development, the design and execution of process development and scale-up experiments, and the transfer of processes to Contract Development and Manufacturing Organizations (CDMO). 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 departmental and company goals.

Job Responsibilities:

- Designs and executes process development and scale-up experiments to support cell isolation, culture, RNA transfection and cryopreservation processes for autologous immune cell therapy products.
- Establishes plans and protocols to develop, troubleshoot, oversee, and support efficient technology transfer of CARMA manufacturing processes to and from the CDMOs and other partners.

- Collaborates with Manufacturing Operations to develop, optimize, and implement new technologies that may benefit CARMA Manufacturing.
- Collaborates with Analytical Development to develop and optimize product-specific analytical test methods to support in-process testing, product characterization, final product release and comparability.
- Contributes to the preparation of regulatory filings as Subject Matter Expert (SME) in process development. Provide data summaries to support other global regulatory activities.
- Provides technical support as needed to help troubleshoot Chemistry, Manufacturing, and Controls (CMC) related issues.
- Maintains up to date knowledge of manufacturing trends and provides recommendations regarding manufacturing process improvement initiatives.
- Contributes to cross departmental activities as needed, by providing technical input where required. Prepares and reviews technical documents for patent applications, regulatory authorities and external contractors and collaborators.
- Develops, revises, and reviews SOPs, protocols, and process development and technical reports.
- Maintains appropriate level of documentation throughout the entire development process and follows Good Documentation Practices.
- Collaborates and manages relationships with cross functional internal and external stakeholders including Research and Development (R&D), Manufacturing Operations, Quality Assurance (QA) and Analytical Development (AD).
- Provides technical and strategic input and drives continuous improvement to the manufacturing process through technological innovation to support ongoing product development efforts by conducting appropriate tests, experiments and qualification studies to justify proposed changes.
- Prepares, reviews, or edits regulatory filing documents and provides responses to questions from US and ex-US health authorities as an SME in process development.
- Complies with all applicable laws and Company policies regarding health, safety, and environment.

Job Requirements:

- Master's degree in Life Sciences or closely related discipline with a strong background in biology/immunology. Bachelor's degree with requisite experience also acceptable.
- 7+ years of experience working in cell/gene therapy, ideally with the majority of that time in process development.
- Demonstrated experience with manufacturing automation and technologies for cell isolation, purification, concentration and cryopreservation.

- Working knowledge and experience with isolating, purifying, culturing, and cryopreservation of PBMCs, T cells and NK cells.
- Strong quantitative, qualitative, and critical thinking skills and abilities. Ability to adapt to changing needs as experiments develop or priorities change.
- Proven experience working with and handling RNA. Experience in mRNA and/or Oligonucleotide synthesis is a plus.
- Working knowledge of analytical instrumentations and test methods, such as qRT-PCR, Flow Cytometry, ELISA and immunological assay is strongly desired.
- Working knowledge of Quality by Design (QbD) is desired.
- Strong troubleshooting skills with the ability to "think outside the box".
- 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.
- Results oriented. Ability to multitask, prioritize work and adapt in a constantly evolving, fast-pace environment with minimal supervision. Solid knowledge of regulatory requirements. Must have working knowledge of pharmaceutical GMP's and ICH guidelines.
- Outstanding written and oral communication skills are essential; ability to present thoughts clearly and concisely.
- Ability to effectively collaborate with and lead vendors, customers, colleagues, and direct reports across teams. Detail oriented with proven leadership, organization and project management skills.
- 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 ***Process Development*** in the subject line.