



Vice President, Regulatory Affairs

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 16 strategic platform licenses to commercial cell therapy developers that allow for more than 95 clinical programs. Founded in 1998, MaxCyte is headquartered in Gaithersburg, Maryland, US.

Job Summary:

Leads the development and execution of MaxCyte regulatory strategy related to MaxCyte's product offerings, inclusive of instrumentation, consumables and reagents. Position responsibilities include managing interactions with and submissions to global regulatory authorities directly and through international consultants and providing regulatory support internally and to MaxCyte's customers and partners. Works collaboratively across functions and teams to develop and implement the Company's global regulatory strategies. Provides regulatory advice and input to internal MaxCyte teams. This individual works under general direction within a matrixed organization.

Job Duties:

- Develops & executes regulatory strategy in support of the business and all product offerings, aligned with company's objectives, timelines, and goals in all countries where MaxCyte operates. Ensures that regulatory strategies meet current and future customer needs and are executed in compliance with current applicable regulations and standards globally.
- Leads and manages interactions (formal submissions, meetings & informal communication) with regulatory agencies, including US Food and Drug Administration (FDA), Health Canada, Pharmaceuticals and Medical Devices

Agency (PMDA) Japan, and others, as needed. Identifies, engages and manages international regulatory consultants as needed to meet the goals of this position

- Maintains and updates existing master files and technical files with regulatory agencies globally. Initiates new master files and technical files as needed.
- Works closely with electroporation system customers and partners to provide letters of authorization (LOA) for IND submissions. Provides regulatory support to customers & partners for successful clinical study & marketing authorizations.
- Maintains an understanding of changes to IND, CTA and marketing application filings specific to commercial cell therapy developers, including master/technical files and alternative approaches of specific regulators in target markets.
- Works with regulatory agencies to develop favorable regulatory pathways for supporting marketing applications of cell & gene therapy clinical treatments using MaxCyte technology.
- Leads and manages interactions with project team members, consultants, contractors and regulatory agencies to ensure all project/programs have clearly defined regulatory paths and milestones. Provides input to manufacturing and new product development teams to ensure regulatory requirements are incorporated into product development and sustaining engineering projects.
- Works with MaxCyte quality leadership to develop and implement robust GXP-compliant processes and supports regulatory requirements related to global distribution of MaxCyte platform technology world-wide. Coordinates with quality function to ensure quality system reflects appropriate US and international standards.
- Represents MaxCyte in biotech industry regulatory forums, presenting MaxCyte concerns & perspectives to industry, as appropriate.
- Maintains current information and awareness of regulatory intelligence, including regulatory agency guidance and procedures, and provides updates to MaxCyte teams. Monitors impact of new and impending regulatory changes and advises management on optimum methods to achieve compliance
- Complies with all applicable policies regarding health, safety, and environmental policies.

Job Qualifications:

- B.S. or advanced degree in a scientific area and at least 15 years of hands-on work experience in regulatory affairs in the life sciences, medical device, and/or biologics manufacturing industry; or equivalent.
- Deep understanding and knowledge of global regulatory affairs principles, practices and systems, especially in the areas of cell and gene therapy CMC, medical devices and manufacturing-enabling technology. Experience creating and maintaining master files is highly desirable.
- History of successful submission of regulatory filings, with acceptance or approval by regulatory agencies, preferably in multiple countries.
- Experience working with customers, vendors, contractors, and global regulatory authorities is required.
- Strong technical/analytical skills and a high degree of personal motivation.
- Ability to read, analyze, and interpret technical dossiers, general business periodicals, professional journals, technical procedures, and governmental regulations.
- Problem-solving orientation with a pragmatic and analytical mind-set driven to deliver solutions.
- Attention to detail and strong leadership, organizational and time management skills.
- Ability to multi-task in a very fast-paced environment.
- Ability to lead and work with cross-functional teams and ensure deliverables are completed on time.
- Excellent communication skills, including writing, verbal, interpersonal skills, and negotiating skills [must be able to effectively communicate with cross functional stakeholders, external vendors, CDMO and quality / regulatory authorities].
- Strong commitment to customer service.
- Ability to travel up to 20%.

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