



Manager, Regulatory Affairs
(Job Code: 2011-6)

Company Overview

ViaCyte, Inc. is a preclinical therapeutic company focused on diabetes. Our therapy is based on pancreatic beta cell progenitors derived from human pluripotent stem cells. These cells are implanted using a durable and retrievable encapsulation device. Once implanted and matured, these cells secrete insulin in response to blood glucose levels. Our goal is long term insulin independence without immune suppression, and without hypoglycemia and other diabetes-related complications.

Our remarkable team has propelled us to the forefront of stem cell research and the advancement of our preclinical studies has created an increased need for regulatory expertise. This is an exciting time at ViaCyte and we invite you to explore this opportunity.

Description

As a member of the product development team, the Manager, Regulatory Affairs will assist with the creation of regulatory strategies aimed at the earliest possible approval of the Company's product applications. Primary duties will include identifying and assessing challenges associated with product development and assisting with strategies to mitigate risks, monitoring product related corporate activities for regulatory compliance, and translating regulatory requirements into practical, workable plans. Another key responsibility will be facilitating the preparation and assembly of submissions to regulatory agencies, including the critical review of supporting documentation, and responses to requests for additional information. Other duties will include organizing meetings with regulatory authorities, assisting with the development and delivery of effective presentations for internal and external audiences, and managing regulatory consultants.

Our work environment is enjoyable for a strong team player who also has the ability to work independently. Our business moves at a rapid pace, making self-motivation and resourcefulness key contributors to success. Flexibility to handle shifts in objectives and timelines is essential. Occasional overnight travel may be required.

Requirements

A bachelor's degree in the biological sciences and a minimum of eight years of relevant industry experience are required. The ability to translate regulatory rules and policies into effective strategies is essential, as is past work with regulatory aspects of clinical trials. Must be knowledgeable of FDA and EU regulatory requirements and processes; and experience working with the FDA Office of Cellular, Tissue, and Gene Therapies is preferred. Experience with combination products (biologic/device or drug/device) is preferred, and an understanding of cell therapy, gene therapy, or stem cell biology is helpful. Must be skilled in Windows and Microsoft Office, including Word, Excel, and PowerPoint. Strong verbal and written communication skills are required.

Application Procedure

ViaCyte is headquartered in San Diego, California. Relocation assistance is not available for this position. Please send your resume or curriculum vitae, with cover letter, to: ViaCyte, Inc., 3550 General Atomics Court, San Diego, California, 92121. Reference Job Code 2011-6 in your correspondence.

For submission by e-mail, please attach your resume or CV, with cover letter, as a Word or PDF file. In the Subject line, please type the Job Code (#2011-6) and your full name. E-mail: hr@viacyte.com