



Process Development Engineer
(Job Code: 2012-1)

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 our transition into development and manufacturing activities has created a need for this new position. This is an exciting time at ViaCyte and we invite you to explore this opportunity.

Description

The Process Development Engineer will contribute to optimizing the design and implementation of processes, instrumentation, and equipment as these systems are transferred from R&D into a regulated manufacturing environment. Primary duties will include determining and verifying manufacturing controls and specifications, collecting and analyzing data, and generating reports to establish and to qualify manufacturing processes. Assisting management with improving techniques and product quality, along with cost effectiveness, is another key responsibility. Additional duties include performing test method and process validations, as required by domestic and international regulatory agencies, along with maintaining accurate records and documentation required to support regulatory submissions. There will be frequent interactions with personnel from other research and manufacturing groups to coordinate product testing, as well as collaboration with the quality assurance department to translate protocols into standard operating procedures.

Our work environment is enjoyable for a team player who also demonstrates strong initiative and 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 work on weekends may be required.

Requirements

A bachelor's or master's degree with five years of industry experience is required. An engineering degree and/or work in medical product manufacturing are strongly preferred. Experience developing and implementing cell-based manufacturing processes is required and work with bioreactors is preferred. Aseptic processing skills are required. Experience writing and implementing equipment validations (IQ/OQ/PQ) and process validations (OQ/PQ) is desirable. Must be skilled in Microsoft Office, including Word and Excel. PowerPoint experience is helpful. Strong verbal and written communication skills are required, including the ability to draft technical reports and to present data clearly and concisely.

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 2012-1 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 (#2012-1) and your full name. E-mail: hr@viacyte.com