Job Title: Process Development Scientist/Engineer

Company Overview – About Avectas

Avectas is an Irish, privately-owned cell engineering technology business currently building out its North American footprint. We are focused on improving the cost, manufacture and patient outcomes for the next generation of cellular therapies. Avectas is developing a unique cell engineering platform, SOLUPORE™, to enable the ex-vivo manufacture of gene modified cell therapy products. SOLUPORE™ produces superior results related to the delivery of molecular cargo and related to improved potency over other delivery technologies. In addition, the technology will facilitate multiple gene edits and is cost-effective and scalable. Avectas is currently developing the clinical (cGMP) technology embodiment while enhancing its dataset, implementing its commercialization strategy, and building out the team.

This role is a unique opportunity at a development-stage company, who are focused on building out their footprint in North America. Avectas is supported with field-leading advisors, and a highly experienced technical/operational team. You will help us to continue to build a transparent and successful organisation focused on delivering our SOLUPORE™ cell engineering platform for the next generation of cell and gene therapies.

Role Overview

The successful candidate will be a highly motivated and experienced scientist/engineer who will be a key member of the technical operations team, working within the Process Development team and closely with both Avectas Scientific and Engineering teams to support the development of the SOLUPORE™ technology and process. This role reports to the Director of Process Development.

Location

MaRS Discovery District, 13th Floor West Tower, Toronto, Canada

Job Title:	Process Development Scientist/Engineer	**Travel Required: (%)**	Yes
Department/Group:	Technical Operations	**Position Type:**	Permanent
Location:	MaRS Discovery District, 13th Floor West Tower, Toronto, Canada	**Date:**	14th October 2020
Level:	4		
Line Manager:	Dir. Of Process Development		

Job Description

Role and Responsibilities

Responsibilities will also include, but are not limited to, the following:

- *Demonstrate technical and scientific expertise in key cell and gene therapy process operations, scale-up, optimisation and qualification.*
- *Demonstrate expertise in cell isolation, expansion (bioreactor) and transfection technologies.*
- *Expertise in process gap analysis / FMEA, generation of process models/workflow.*
- *Independently planning and executing experiments to generate technical data to support scale-up and implementation of processes.*
- *Conducting test protocols and procedures for product evaluation, advising on equipment modifications to enable process changes for new product development.*
- *Qualifying new processes and demonstrating improvements with data, technical reports and maintenance of appropriate records.*
- *Author / review Process Descriptions and Batch Records, author / review change controls, perform process monitoring (manufacturing data summary and analysis, data presentation), author summary reports, perform activities to assess deviations and process changes.*
- *Identifies potential root causes using a systematic approach using a variety of problem-solving tools e.g. Fishbone etc. able to identify potential solutions.*
- *Performs or can understand all types of data analysis such as ANOVA, multivariate analysis.*
- *Communicating information on current process data which may impact process/product development.*
- *Supporting internal and external technology transfer and training on new products and processes.*
- *Supporting technology transfer activities and process validation activities as required at partner companies/CMOs including Gap Analysis and Process Transfer Risk Assessment.*
- *Lead major process investigations as requested and support the implementation of CAPAs.*
- *Engage in all required Departmental meetings and working closely with cross-functional teams.*
- *Liaise with site functions –Operations, Project Management, Engineering, Process Development to support the process transfer.*
- *Liaising and communicating with Director of Process Development daily basis.*
- *The role will require flexibility to travel to sites in Canada/US/Europe and to project meetings away from site.*

Skills/Knowledge/Experience Required:

Qualifications & Experience:

- BSc is a minimum M.Sc/Ph.D and/or industrial experience is desired.
- Experience of cell culture of human and/or mammalian cell lines is essential.

- Experience of upstream and downstream bioprocessing, ATMP manufacturing and/or process development environment.
- Experience in equipment or process qualification and validation and knowledge of technology transfer (IQ/OQ/PQ) is desired.

One or more of the following will be advantageous to applicants:

- Experience/understanding of operating within a Good Manufacturing Practice (GMP) environment.
- Knowledge of FDA and additional multi-jurisdictional regulatory guidelines (HC, EU, PMDA, etc.) on method development/validation.
- Experience in Flow cytometry.
- Experience in the development of analytical assays suitable for use as characterisation, QC release methods and in-process controls is desirable.

Skill and Competencies:

- Excellent interpersonal skills and good ability to multitask.
- Strong communication skills, both verbal and written.
- Strong evidence of problem-solving/troubleshooting skills.
- Can work both independently and as part of a dynamic team.
- An enthusiastic ambitious positive self-starter with an ability to build relationship with external Contract Manufacturing Organisations and developer companies.
- Highly motivated with an ability to take ownership and with strong attention to detail.
- Ability to work under pressure.

Prepared By:	Lisa O'Flynn	Date:	14th October 2020

How to Apply:

Application should include:

- A letter of interest.
- Complete curriculum vitae

To apply for this position please address all materials to **Lisa O'Flynn, loflynn@avectas.com.**

This post will stay active until the position is filled. We would like to thank all applicants, but only those selected for an interview will be contacted.