**Position**

Process Development Senior Scientist/Engineer

**Location**

Ground Floor Building 10, Cherrywood Business Park, Co. Dublin, D18 T3Y1

**Company Overview**

Avectas is a cell engineering technology business focused on improving the cost, manufacturing, 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 is a patented, non-viral, cell engineering technology that permeabilizes the target cell membrane and allows efficient transfer of cargo into cells while retaining very high levels of cell viability and functionality.

**Position overview**

The successful candidate will be a highly motivated and experienced process scientist/engineer who will be a key member of the technical operations team and deeply involved in leading the development of new processes. The candidate working within the Process Development team will also liaise 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.

**Responsibilities:**

- Support scientific activities focused on process development demonstrating technical and scientific expertise in key cell and gene therapy process operations, scale-up, optimisation and qualification.
- Demonstrated expertise in cell isolation, expansion (bioreactor) and transfection technologies.
- Design experiments independently and in multi-disciplinary team to efficiently test hypotheses, rapidly iterate to ensure optimal solutions and implementation of processes.
- Execute experimental plans individually and with the team.
- Conduct test protocols and procedures for product evaluation, advising on equipment modifications to enable process changes for new product development.
- Expertise in process gap analysis / FMEA, generation of process models/workflow.
- Drives key initiatives including trouble-shooting manufacturing challenges.
- Qualify new processes and demonstrating improvements with data, technical reports, and maintenance of appropriate records.
- Identify potential root causes using a systematic approach using a variety of problem-solving tools e.g. Fishbone etc. able to identify potential solutions.
- Perform 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.
- Author / review work instructions, protocols and Run/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.

- Execution and support of technology transfer activities and process validation activities as required internally and at partner companies/CDMOs.
- 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.
- Liaise and communicate 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.

**Qualifications & Experience:**

- M.Sc/PhD and/or industrial experience with a focus in Cell and Gene Therapy research and development is desired.
- Experience in a Cell and Gene therapy company or R&D environment
- 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.
- Experience working in a small-medium company and/or facility start-up.

**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.

**Job Type:** Permanent

**How to Apply:**
Letter of interest and complete CV addressed to Dir of Process Development Kartik Srinivasan ksrinivasan@avectas.com
The 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.