Senior Design Engineer

Background:

Avectas is a privately-owned cell engineering technology business, 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 cell health and potency over other delivery technologies. 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 well-funded start-up, 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.

The Role:

We are looking for a talented, experienced Senior Design Engineer to join our team as a key contributor to Technical Operations supporting our internal and external Cell Therapy programs. As a Senior Engineer at Avectas, you will have a key program-based role.

Reporting directly to the Director of Process Engineering the Senior Design Engineer will provide high quality engineering and design support to the Technical Operations team. The ideal candidate will be action-oriented and a key team member with a strong understanding of design engineering space.

Location:

Maynooth with the ability to work remotely when appropriate to the work program.

Job Title:	Senior Design Engineer	**Travel Required: (%)**	Up to - 50 %
Department/Group:	Process Engineering	**Position Type:**	Full Time Permanent
Location:	Avectas, Maynooth with capacity for partial remote working as appropriate	**Date:**	7 July 2022
Level:	4		
Line Manager:	Director of Process Engineering		

Job Description

Role and Responsibilities

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

- Lead Avectas design activities throughout the entire product life cycle from concept to specifications to prototyping, commercialisation and retiring.
- Lead and participate in common engineering risk workshops including safety risk assessments and dFMEAs.
- Draft and maintain engineering related protocols and work instructions in line with the Avectas QMS.
- Develop and review technical documentation in compliance with the Avectas QMS including CAD, drawings, manuals, SOP's, design briefs, technical reports, test strategies, test protocols, specifications etc.
- Build and maintain design history files for Avectas technologies.
- Lead engineering activities and liaise with Avectas appointed contract and development manufacturing organisations (CDMOs).
- Design and develop prototype solutions for challenges across the spectrum of Avectas technologies.
- Incorporate existing knowledge from Avectas into appropriate aspects of design.
- Build instruments in compliance with international medical, electrical and mechanical standards.
- Design engineering experiments to test design performance using statistical methods and software.
- Represent Avectas in design decisions (internally and with CDMOs) and ensure all designs and solutions consider "design for manufacture".
- Provide technical guidance to colleagues and on all areas of a design.
- Communicate design decisions, progress and impact to other Avectas colleagues.
- Own project deliverables and work packages, working in tandem with Project and Vendor Management to ensure delivery on time, in full and on budget.
- Conduct installation, commissioning, and qualification of Avectas technologies internally and externally at Avectas partner sites or appointed CDMOs.
- Identifying suppliers for materials, components and subassemblies as required.
- Design and implement jigs and test rigs to aid in Avectas product development and testing
- Support and enhance the design documentation process at Avectas and ensure appropriate level of documentation is supported by and transferred from external partners and CDMOs.
- Operate in a team environment, assume leadership roles in cross functional teams.
- Provide timely, accurate and concise summaries and project reviews to the Director of Process Engineering.
- Travel externally to Avectas appointed CDMOs, suppliers or partners to conduct technical audits.

Experience and Requirements:

- Degree level qualification in Product, Mechanical, Manufacturing, Mechatronic or Biomedical Engineering.
- 7-9 years post graduate experience with 5 years in a regulated industry such as Medical Devices, Pharmaceuticals or Biotech. Experience in another highly regulated industry will also be considered.
- Strong understanding of regulated documentation systems aligned with ISO13485.
- Demonstrated history of product design and prototyping ideally with electronic and pneumatic elements.
- Comfortable working with common engineering measurement tools such as oscilloscopes, DAQ systems multimeters, transducers and manometers.
- Experience using PLCs and ladder logic an advantage.
- Strong experience with common product design and CAD software; ideally Solid Edge, photoshop and Illustrator.
- Demonstrated history of instrument qualification (FAT, IQ, OQ and PQ) as well as Verification and Validation.
- Experience using and knowledge of statistical packages to design experiments, ideally Minitab.
- Experience designing products to international standards (EN IEC 61010, 60204, 60601) for CE marking.
- Experience working in compliance with a Quality Management System and the capability to draft documents at the appropriate level (SOP, WI etc).
- Experience building and maintaining technical regulatory documents including design history files.
- Knowledge of injection moulding highly desirable.
- Experience with basic computer programming for task and data analysis automation desirable, for example Excel VBA or Matlab.
- Demonstrated history of leading technical aspects of a project both internally and with external partners.
- Excellent communication skills and demonstrated experience of liaising with external vendors and clients.
- Familiarity with GMP qualification of equipment.

Prepared By:	Shane Finnegan	Date:	7 July 2022