

JOB DESCRIPTION

Title: Product Development Engineer, for Kytopen

Overview

[Kytopen](#) is an MIT spinout streamlining the engineering of a wide array of human and human-derived cells for use in next-generation cell therapies, with the goal of expanding access to powerful new living medicines. We enable transformative therapies with our patent-pending continuous *Flowfect*[®] cell engineering platforms. The non-viral *Flowfect*[®] technology is a fast, scalable, and gentle process that yields billions of high-quality engineered cells in minutes while maintaining cell health and function. We seek passionate, pioneering people to join the team on this mission.

Summary

The Product Development Engineer will have responsibility for execution of various product development engineering efforts for Kytopen. The qualified candidate will demonstrate the ability to effectively execute technical development in the areas of mechanical and electrical systems as required for the development of the Kytopen technology components and systems. This individual will work in coordination with internal and external personnel as needed.

Qualifications and Skills

The ideal candidate will be a high energy, confident individual possessing strong analytical and communication skills with a B.S. in an engineering discipline, with at least 5 years industry experience.

Responsibilities and Duties (What we need)

- Identify critical requirements of the technology, in tandem with Engineering and Biology leadership, and design and build solutions to meet these requirements
- Capture design intent in manufacturable drawings, with appropriate use of GD&T and Critical to Quality features as needed
- Identify and interpret the appropriate regulatory standards and guidelines driving design
- Mentor co-ops and interns, serving as subject matter expert in engineering and technical best practices
- Work with external partners and suppliers to seamlessly coordinate technology development
- Use software and hardware techniques and tools to enable efficiencies and technical excellence throughout engineering efforts
- Understand and utilize Design Excellence / Six Sigma approach in design and development of systems
- Identify testing needs and approaches, develop test methods, execute necessary testing, with clear documentation of results and impact
- Write and update protocols, reports, procedures as necessary to support Engineering and Development efforts

Requirements (About you)

What:

- B.S. in engineering discipline, preferably mechanical, biomechanical engineering, or related discipline
- At least 5 years of industry experience developing for medical device, diagnostic, or pharmaceutical (process equipment or process development) systems
- Experience developing at least one commercial product from concept to commercial launch
- Familiarity and experience working in a regulated environment and building products according to Industry Standards
- Familiarity and demonstrated excellence designing complex electro-mechanical systems, including concept, prototyping, drafting, assembly, component qualification and testing (including verification and validation)
- Strong organizational, analytical, problem-solving, root-cause-analysis, and trouble-shooting skills
- Strong written and verbal communication skills

How:

- Ability to work within a diverse workforce and provide a positive and motivational work environment
- Scientifically motivated with the ability to design, conduct, and analyze experiments
- Entrepreneurial and comfortable in a fast-paced environment
- Ability to adapt to shifting constraints while maintaining high performance and morale
- Self-motivated and collaborative, with excellent time management
- Creative and adaptable in identifying and implementing best practices across team
- Demonstrated leadership ability to exemplify Kytopen's values of: Impact, Passion, Integrity, Resilience, and Inclusivity

Preferred (More about you...)

- Experience launching products within US FDA GMP/GLP, ISO13485, CE, and other regional regulations and requirements
- Cell and gene therapy device manufacturing experience preferred, but not required
- Six Sigma certification