KYTOPEN

JOB DESCRIPTION

Title: Senior Quality 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 gene delivery 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 Senior Quality Engineer will be responsible for supporting the introduction of new quality systems and inspection processes that will be implemented throughout the organization. This role will support Engineering projects and drive towards continuous improvement in Quality. Given Kytopen's status as an early stage company, this role will also require hands on efforts supporting product testing activities. The successful candidate will provide Quality Engineering support in design, development, and manufacture of new components and products, as well as plan, organize and execute engineering protocols and generate documentation according to Quality Procedures.

This position will report directly to Kytopen's Quality Leader and will have an indirect reporting line to Head of Research & Development.

Qualifications and Skills

The ideal candidate will be a high energy, confident individual possessing strong communication skills, with a degree in a Technical or Applied Science discipline and at least 5 years engineering experience in life sciences or medical device industry.

Responsibilities and Duties (What we need)

Responsibilities Supporting Engineering Objectives

- Create and execute quality system procedures and protocols to ensure all product, material, parts, and documentation are compliant with company specifications and quality standards.
- Perform and review engineering inspection and testing, verification, and validation, and document work in compliance with established procedures.
- Review and approve engineering changes and drawing revisions.
- Serve as a Subject Matter Expert (SME) for Geometric Dimensioning and Tolerancing (GD&T) and Statistical Process Control (SPC).
- Initiate Quality document revisions including inspection plans and procedures.
- Actively contribute to ongoing continuous improvement efforts and projects, and drive products and processes toward continuous quality improvement.
- Provide input on Quality System requirements in support of regulatory and quality requirements.

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Responsibilities Supporting Quality Management System (QMS) Objectives

- Support and/or lead investigations for Complaints, Deviations and Corrective Actions.
- Support internal, customer and third-party audits.
- Maintain current product data records, including drawings and specifications.
- Perform Document Control to ensure complete, consistent, and compliant records.
- Assist with performance and documenting of change controls and risk assessments.
- Assist with assembly and maintenance of regulatory submissions.

Requirements (About you)

What:

- B.S. in a Technical or Applied Science discipline
- Minimum of 5 years engineering experience developing and manufacturing process equipment in the life sciences industry or medical devices, with robust working knowledge in applicable regulations
- Applied knowledge of Geometric Dimensioning and Tolerancing (GD&T) and Statistical Process Control (SPC)
- Experience with hard gauging and hand tools for taking measurements
- Strong planning and problem-solving skills
- Strong communication and collaboration skills
- Strong technical writing skills, including creation of work instructions / procedures, testing protocols and reports
- Basic knowledge of 5S methodology

How:

- Ability to work within a diverse workforce and provide a positive and motivational work environment
- Entrepreneurial and comfortable in a fast-paced environment
- Ability to adapt to shifting constraints while maintaining high performance and morale
- Ability to interface collaboratively with internal and external customers
- Self-motivated and collaborative, with excellent time management
- Demonstrated leadership ability to exemplify Kytopen's values of: Impact, Passion, Integrity, Resilience, and Inclusivity

Preferred (More about you…)

- Six Sigma Black Belt certification
- Experience working in cleanroom and wet-lab environments
- Familiar with ERP, LIMS, and ELN software