Systems Engineer – Quality and Testing

Rec # 1031

Category: Engineering
Job Type: Full Time, Exempt
Location: Onsite – US – Michigan – Ann Arbor

Building tools to isolate cells and understand their behavior is what we do. Are you looking to push past traditional boundaries and scale your potential? We are growing and seeking talented people to help us make a difference.

Celsee, Inc., a privately held company in Ann Arbor, Michigan, is breaking through the traditional barriers of single-cell analysis and delivering clinical-grade technology designed to support the life sciences revolution and precision medicine. Based on a gentle, gravity-induced, micro-well isolation technique, the patented technology forms the foundation for a scalable and flexible single-cell analysis platform that makes more experiments feasible. Celsee's first product, the Genesis system, enables scientists to analyze and interpret cellular behavior and collect previously inaccessible information for improved results in applications such as proteogenomics, next-generation sequencing, immune monitoring, and cell therapy.

Summary:

Celsee is seeking an experienced individual to join our innovative Systems Engineering team. In this cross functional role, you will participate in product development and transfer activities for complex system and instruments. You will ensure product and process conformance to applicable safety and quality regulations and standards. You will be responsible for guiding teams in execution of design control activities with focus on new product development quality planning and risk management to positively impact the safety and efficacy of products. Additionally, you will work in teams identifying, documenting assessing, correcting and preventing quality issues using risk analysis, root cause analysis tools, DFSS concepts from initial product concept through transfer to sustaining.

Key Responsibilities:

- Lead quality initiatives aligned on new product development teams, with a focus on systems and instruments.
- Facility process in the areas of design control, design verification and validation, design transfer, process validation, risk management, and specification development.
- Aid in the assessment and qualification of raw materials, including development of component specifications and inspection standards.
- Drive product risk management activities and ensure quality and completeness of project design history files, validation packages, and change orders.
- Ensures adequacy of complaint, non-conformances and CAPA records, investigations, and corrective actions during transfer activities.
- Ensure product development and validation programs meet requirements when applicable.

- Analyze and report on quality data in order to improve product and process; develop recommendations based on data analysis.
- Provide management with status updates on assigned responsibilities and goals and escalate issues in a timely fashion

Position Accountability/Scope:

Position reports to the Director of Engineering and works on all assigned tasks/projects that are within scope for the defined position.

Required Education and Experience:

- Bachelor's degree in Engineering or technical science discipline, advanced degree preferred experience.
- 5-8+ years' experience in quality & test field in a regulated environment; direct experience working in in-vitro diagnostic preferred.
- Practical experience in design controls, risk management, verification, validation and change control, and failure investigation tools and techniques
- Experience applying quality regulations and standards (e.g. 21CFR 820, ISO 13485, ISO 14971, IEC62304, GAMP5, IVDD, ISPE Baseline Guides, and ASTM E2500-07 Verification Guideline)
- Proven history of successfully preparing products for transfer activities.
- Demonstrated ability to accomplish goals while working across departments and teams.

Work Environment:

Most work is performed in an indoor office, engineering lab and biochemistry wet lab environment. Minimal travel to local suppliers or consultants is required.

Physical Demands:

Occasional lifting of up to 50 pounds.

How to Apply:

For consideration, please submit CV & salary requirements to careers@celsee.com, mention the job description in the subject. No phone calls please. Only qualified candidates will be contacted.

Celsee is an equal opportunity employer, and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability status, protected veteran status or any other characteristic protected by law.