ABOUT US:

Biodesix is a leading diagnostic solutions company with a focus in lung disease. The Company develops diagnostic tests addressing important clinical questions by combining multi-omics through the power of artificial intelligence. Biodesix offers five Medicare-covered tests for patients with lung diseases. The blood based Nodify Lung® nodule risk assessment testing strategy, consisting of the Nodify XL2® and the Nodify CDT® tests, evaluates the risk of malignancy in pulmonary nodules, enabling physicians to better triage patients to the most appropriate course of action. The blood based IQLung™ strategy for lung cancer patients integrates the GeneStrat® targeted ddPCR™ test, the GeneStrat NGS® test and the VeriStrat® test to support treatment decisions across all stages of lung cancer with results in an average of two to three business days, expediting the time to treatment. Biodesix also leverages the proprietary and advanced Diagnostic Cortex® AI (Artificial Intelligence) platform, to collaborate with many of the world's leading biotechnology and pharmaceutical companies to solve complex diagnostic challenges in lung disease. For more information about Biodesix, please visit www.biodesix.com.

OBJECTIVE OF THE POSITION:

The Design Quality Engineer II collaborates with other staff on the product design, research and development, marketing and manufacturing teams to create highly functional products or services that are aligned with the company's goals and mission.

This position manages quality policies, procedures, processes, programs, and practices associated with product realization activities (including pre and post launch) and documentation to demonstrate conformance with appropriate standards and regulations. The Design Quality Engineer II is responsible for supporting product development teams in the design practices and risk and hazard management processes associated with development of specimen collection kit, assays, diagnostic test services and software algorithms per the Biodesix Quality Management System (QMS).

The Design Quality Engineer II is responsible for ensuring that a product meets the company's standards and the specifications in each product lifecycle. This position will collaborate with the design and production teams on various design projects. In addition to being a good communicator, all candidates should be creative thinkers with excellent problem-solving skills.

RESPONSIBILITIES:

- Apply Design Controls Management knowledge to product design and phase gate reviews, as well as Design History File (DHF) updates, by reviewing and approving technical documentation such as design and development plans, artwork and labeling, validation/verification protocols, reports, and records.

- Review and approve New Product Development project deliverables, as well as product optimization deliverables, for compliance, completeness, and consistency, with a focus on "Design for Quality."
- Acting Quality function for product optimization and development core teams responsible for documenting the design process and presenting progress reports to all relevant stakeholders.
- Generate and maintain risk documentation, including, but not limited to Hazard Assessments, Risk Assessments, and Risk Reports, and be a strong contributing team member to Failure Mode and Effects Analyses (FMEA's).
- Assist in the development of statistically rationalized component and product acceptance inspection plans.
- Analyze data using tools such as Capability Analyses/Studies, SPC, and trend analyses to update inspection plans and control plans.
- Evaluating design plans to comply with industry standards and regulations.
- Maintain existing quality records and designs including development and maintenance of all product DHFs.
- Assist in the development of Quality Management System (QMS) processes and procedures to ensure compliance with applicable design control and product development regulations.
- Perform data analysis, and develop, monitor, and oversee metrics reporting.
- Lead and/or support continuous improvement activities.
- Support and participate in internal and external audits and inspections.
- Generate and maintain procedures, work instructions, inspection plans, forms, and templates.
- Lead and/or participate on Corrective Action and Preventive Action (CAPA) investigations.
- Review/approve verification & validation protocols and reports.

COMPETENCY OR POSITION REQUIREMENTS:

- A strong working knowledge of ISO 14971 and ISO 13485.
- A working knowledge of Design Controls Management (21CFR820.30) practices and procedures (Design & Development Planning, Design Input, Design Output, Design Review, Design Verification & Validation, Design Transfer, Design Changes, and Design History File).
- Familiarity with quality engineering concepts and tools, e.g. Statistical Process Control (SPC), Capability Analyses, Design of Experiments (DOE's), and Process Control Plans (PCP).
- Demonstrated application of statistical tools and techniques.
- Knowledge of external standards and regulations pertaining to medical devices, specifically the European Medical Device and In-Vitro Diagnostic Regulations (EU MDR/IVDR), and Usability standards is preferred.
- Competency in Microsoft Office (SharePoint, Teams, Word, Excel, PowerPoint)
- Excellent written and verbal communication skills.
- Accurate and strong attention to detail.
- Ability to multitask and manage time effectively.
- Strong problem solving, root cause analysis and analytics skills.

EDUCATION AND EXPERIENCE:

- Bachelor's degree in design engineering, engineering, product design, or relevant field.
- A minimum of 3 years' experience in a similar role.

REGULATORY REQUIREMENTS:

This role shall comply, at a minimum, with the responsibilities and qualifications outlined in:

- CLIA: Clinical Laboratory Improvement Amendments (CLIA) Requirements, Title 42 Code of Federal Regulations Part 493
- CAP: College of American Pathologists (CAP): All Common, General, Director Responsibility and Authority and all test-specific checklists
- NYS CLEP: New York State Department of Health, Clinical Laboratory Evaluation Program (CLEP), New York State Public Health Law, Article 5 Title 5
- ISO: International Organization for Standardization (ISO) 13485, Quality Management Systems, Requirements for Regulatory Purposes, 2016
- All other applicable state and regulatory governing authorities including but not limited to: CA, PA, RI, MD

PHYSICAL REQUIREMENTS:

- The physical demands described here are representative of those that must be met by a team member to successfully perform the essential functions of this job.
- Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.
- While performing the duties of this job, the team member is regularly required to use hands to grip, handle, or feel objects, tools, or controls and talk or hear.
- The team member frequently is required to sit, walk, and reach with hands and arms; occasionally is required to stand, stoop, kneel, crouch, or crawl, and must occasionally lift and/or move more than 25 pounds.
- Specific vision abilities required by this job include visual acuity to Colorado driver's license requirements.

WORK ENVIRONMENT:

- The work environment characteristics described here are representative of those a team member encounters while performing the essential functions of this job.
- Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.
- The primary work environment is an office setting.
- The noise level in the work environment is usually moderate.

UNPLANNED ACTIVITIES:

- Other duties as assigned.

TRAVEL PERCENTAGE:

- Up to 15% travel.

COMPENSATION:

We are excited to provide:

- Competitive compensation $83,800 - $98,600
- Individual base compensation is based on various factors unique to each candidate, including skill set, experience, qualifications, and other job-related aspects.
- Discretionary Bonus opportunity
- Comprehensive benefits package – effective date of hire
- Medical
- Dental
- Vision
- Short/Long Term Disability
- Life Insurance
- Flex Spending Account
- 401(k)
- 120 hours of annual vacation
- 72 hours of paid sick time off
- 11 paid holidays
- 3 floating holidays
- Employee Assistance Program
- Voluntary Benefits
- Employee recognition program

JOB LOCATION:

- Louisville, CO

Biodesix is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, or veteran status.