Job Opening for: Senior Research and Development Engineer

Position Overview
The Senior Research and Development Engineer is responsible for leading the development and design of new and existing products while collaborating with peers. This role will create and maintain technical documentation that includes specifications, design drawings, test plans and reports in accordance with design control procedures. This position reports to the Director of Engineering and is a hybrid role with a minimum of 3 days on site in Pittsfield and/or Guilford, ME.

Responsibilities
- Support design and/or process alterations to existing specimen collection products.
- Spearhead and execute modifications and changes to products to improve and optimize performance.
- Investigate product design and reliability issues in partnership with other cross-functional teams.
- Lead or assist in efforts to grow manufacturing/supply chain capacity.
- Support product production through the commercialized life cycle.
- Design and test prototypes to establish robust product performance.
- Partner closely with manufacturing and quality engineers to incorporate design for manufacturability.
- Develop and validate new test methods and/or alter existing test methods.
- Develop design inputs and design outputs for changes to existing or new distributed product.
- Plan and coordinate aspects of work by preparing, participating, and leading design reviews.
- Contribute to leadership of design efforts and the verification and validation of new product designs.
- Support process validation for processes and products including IQ, OQ, and PQ.
- Support risk management activities and risk management reviews on existing products.
- Lead Design Change activities for the organization per Design Control requirements.
- Provide support for non-conformance investigations regarding component failures, finished goods failures, and product returns.
- Provide support for customer complaints and CAPA.
- Support regulatory approvals and responses to regulatory questions for existing products.
- Maintain and supplement design history files that are thorough and accurate for existing product.

Qualifications/Education/Experience
- Strong mechanical design and analysis skills
- Proficiency in SolidWorks or similar software
- Proficiency in all phases of product development including design, implementation, verification, validation, and manufacturing.
- Exceptional verbal and written communication skills.
- Familiarity with ISO 13485, MDR, and FDA QSR.
- Proven ability to take initiative and work independently from objectives.
- Proven problem solving and trouble shooting skills.
- Bachelor's degree or higher in mechanical engineering or degree equivalent, with a minimum of 5 years relevant work experience.
- Experience in regulated environment (auto, food & beverage, medical devise) ISO 13485 preferred.
- Experience with quality management systems and medical device regulations.
- Knowledge of clinical applications and associated product requirements with the ability to translate these requirements into detailed specifications.

Physical Requirements
- Occasionally lift 50 lbs. and regularly lift to 30lbs, handle tasks involving frequent bending, twisting, lifting, squatting, walking, and standing.
- Must be able and willing to work in a fast-paced environment.
- Must be able to use fingers to grasp, move, or assemble small objects.
- Prolonged periods sitting at a desk and working on a computer.

This position offers a competitive salary, opportunities for career growth, and a dynamic work environment. If you have a strong background in production management and possess the necessary skills, we encourage you to apply for this exciting opportunity.

Job Type: Full-time, Salaried
Pay: Starting from $85,000.00 per year