POSITION: Design Assurance Engineer

REPORTS TO: Product Manager

LOCATION: Louisville, KY

ORGANIZATION BACKGROUND/CULTURE

Vivorté, Inc. is an orthopedic medical device company. Our mission is to identify, design, develop and commercialize innovative orthopedic devices to improve the lives of patients. Vivorté's focus is to maintain or improve bone strength while expediting the healing process. The company has a firm commitment to provide high quality, unique technologies that lead to superior patient outcomes and cost-effective solutions for surgeons, hospitals and payers. We are a team-oriented organization with motivated associates who are committed to continuous improvement and growth.

POSITION SUMMARY

Vivorté is searching for an individual with medical device experience to help the team navigate and execute design and process controls. This individual will be responsible for implementing development projects into Vivorte's Quality Management System and supporting changes to current marketed products. This individual will work cross-functionally with other departments to assure proper validation and verification activities, and act as a liaison between product development and quality/regulatory divisions.

This role is responsible for providing technical engineering support to new product development teams and sustaining manufacturing / operations teams. This individual is expected to apply knowledge of design and process control principles and quality engineering techniques to design, transfer and manufacturing activities. As a member of one or more cross-functional teams, this individual will assist in mitigating risks throughout the product's life cycle and preparing design and process verification and validation protocols and reports. In parallel, this person shall ensure products are developed in accordance with applicable regulatory requirements, customer expectations and industry standards.

As in any small company, all employees may be required to assist with business development, testing, manufacturing, documentation, regulatory, and clinical.

Additional duties may be assigned to this position on an as needed basis to ensure success of the company.

KEY RESPONSIBILITIES

- Provide quality guidance pertaining to manufacturing, product development, international registration, design and process controls, etc.
- Support product lifecycle management.
- Perform DMR and DHF compliance assessments to ensure quality and regulatory requirements are successfully implemented and maintained.
- Utilize statistical process control methodologies to achieve required levels of product reliability.

- Support design/process verification and validation studies on new products and existing products. Plan and execute re-validation and/or verification activities when process improvements are made to existing products.
- Collaborate with internal departments (Quality, Design/Product Development, Research, Marketing, Regulatory, Clinical and Management) and external groups (clinicians, consultants, regulatory agencies and other organizational partners) to assure appropriate quality requirements.
- Execute a risk-based approach to design requirements/specifications, technical standards, test methods, supplier controls and manufacturing controls complying with appropriate regulations, standards and guidelines.
- Coordinate, assess impact and implement supplier changes.
- Assess the regulatory risk associated with change documents
- Create test protocols, work instructions and reports for improved processes as required by the FDA and ISO standards for regulated medical devices.
- Support new product transfer from development to production.
- Active participation during internal and external audits and ensure compliance with all ISO/FDA requirements for medical devices.
- Support Operations in day-to-day production activities including but not limited to receiving inspection of product components, manufacturing of component and finished goods, batch release testing and inspections.
- Must be able to reach, bend and lift up to 35 lbs on a daily basis.
- May need to work in a bench setting, lab setting, manufacturing floor or clean room environment.
- Perform other duties assigned as needed.

CANDIDATE QUALIFICATIONS & PROFESSIONAL EXPERIENCE

- BA/BS degree in engineering or science curriculum required; advanced degree preferred.
- Two plus years in QA/Regulatory or Design with medical device company; orthopedic or biologic experience a plus.
- Demonstrated knowledge of FDA Quality System Regulation, ISO 13485 Quality Management System and ISO 14971 Risk Management for Medical Devices.
- Thorough understanding of implementation of design and process controls and changes.
- Experience in complying with Design and Process Controls requirements and expectations.
- Experience working with new product design / development projects or sustaining engineering projects.
- Excellent knowledge of regulatory design/development requirements.
- Knowledge and familiarity with engineering product development and commercialization.
- Understanding of mechanical and biologics engineering a plus.
- Familiarity with mechanical drawings, quality systems, documentation and record keeping, ISO 9000, ISO 13485 and/or cGMP 21 CFR a plus
- Working knowledge of Microsoft Word, Microsoft Excel, Windows
- Able to constructively collaborate with cross-functional teams

CORE COMPETENCIES

- Strong organizational skills and ability to prioritize workflow to meet established time frames and schedules.
- Excellent follow up, detail oriented and demonstrated strong quantitative skills.
- Excellent communications skills and willingness to provide honest, effectual program feedback.
- Ability to thrive in a flexible small company environment with direction but limited direct supervision.
- Must be able to manage and prioritize multiple tasks to deliver on commitments.
- Willing to support the team with tasks outside the job description.
- Takes ownership and is accountable for keeping company in good standing with all quality and regulatory guidelines while balancing the commercial needs of the company.
- Constantly seeking opportunities to improve the way the company operates.

COMPENSATION AND BENEFITS

Vivorté offers a competitive salary based on requisite skill and experience level, plus employee benefits including medical, dental, vision, short-term and long-term disability and life insurance following 90 days of employment.

As part of the standard hiring process, employment will be contingent upon successful completion of a background check.

TO APPLY

Interested candidates should send resume and salary requirements to info@vivorte.com. Qualified applicants will be responded to as quickly as possible.

Please note: Applicants for employment in the U.S. must possess work authorization that does not require sponsorship for a visa now or in the future. Vivorte, Inc. is an Equal Opportunity Employer. Vivorte does not discriminate on the basis of race, religion, color, sex, gender identity, sexual orientation, age, non-disqualifying physical or mental disability, national origin, veteran status or any other basis covered by appropriate law. All employment is decided on the basis of qualifications, merit, and business need.