

O. 502.714.7234 F. 502.805.0721 vivorte.com

1044 East Chestnut Street Louisville, KY, 40204

POSITION: Paid Biomedical Engineering Internship/Co-op

REPORTS TO: Product Engineer

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

Under the direction of the Product Engineer, support the design, process, and quality functions in product development and commercialization of new medical devices and support Manufacturing in the production of existing product lines using expertise in biomedical engineering.

KEY RESPONSIBILITIES

- Support Operations in day to day production activities including but not limited to receiving inspection of product components based on pre-determined risk levels, manufacturing, quality controlled inspection testing during batch release to maintain product and process effectiveness.
- Perform manufacturing in controlled environment rooms per validated standard operating procedures which may require the handling of chemicals and human tissue.
- Support Product Engineer to draft drawings, draft manufacturing procedures, standard operating procedures for new medical devices.
- Support Product Engineer to design, prototype and create medical device manufacturing aids.
- Ensures all work in compliance with regulatory requirements per Vivorté's Quality Management System.
- Identify process/product non-conformances, create, and execute required corrective-preventive actions.
- Support design/process validation studies on existing products, as needed.
- Support design/process validation on new medical devices products at Vivorté, or as needed.
- Design and validation of company's orthopedic devices.
- Engineering design support for achieving design freeze and regulatory submission documentation/evidence.
- Ensure all medical device design documentation is in compliance with current requirements and meets required submission standards for approval.
- Support Manufacturing for the receiving inspections, installation, qualification, operation and maintenance of manufacturing tools, production, and inventory facilities.
- Ensure development lab policies and procedures are met as required by GLP, GMP, and OSHA regulations.
- Support operations in identifying qualified and sustainable supplier partners for raw material, processing, testing, and manufacturing.



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- Implements design for manufacturability and cost containment processes.
- Accurate and timely design, testing and processing documentation and reporting.
- Maintain lab notebooks and data.
- Completes required safety, quality and compliance training as needed.
- Any other duties as assigned for the success of the company.

TECHNICAL ASSISTANCE:

• As in any small company, employee may be required to assist with basic technology development: record keeping, testing, transporting materials, performing internet research, sourcing materials, etc. Training will be provided.

CANDIDATE QUALIFICATIONS & PROFESSIONAL EXPERIENCE

- High school degree or equivalent required
- Working knowledge of Microsoft Word, Microsoft Excel, SolidWorks/Other CAD software preferred

TO APPLY

Interested candidates should send resume to aosbourne@vivorte.com. Qualified applicants will be responded to as quickly as possible.