



POSITION SUMMARY

The Product Development Engineer is responsible for contributing to the design and development of new products, product line extensions, and expansion of claims on existing products, and working with a cross-functional team through the product development life cycle. Scope of work may include prototype development, bench testing, pre-clinical studies, academic literature reviews, regulatory and quality support, or other efforts.

EDUCATION

- Bachelor's degree in biomedical/biological engineering, biology, or related field required. Master's or PhD degree preferred.

EXPERIENCE

- Preferred 1-2 years of experience in FDA/GMP and ISO 13485 environment in medical device industry
- Demonstrated knowledge of FDA Quality System Regulations and ISO 13485 based quality management systems
- Comfortable operating within defined quality/regulatory requirements and following standard practices and procedures
- Strong technical design capabilities and analytical and problem solving skills
- Experience with project management principles

PRINCIPAL RESPONSIBILITIES (Other duties may be assigned)

- Work with Product Management to interpret market feedback and prioritize and manage execution of product development and product enhancements, including claims/labeling expansion, product line extensions, updated marketing materials, etc.
- Create and communicate project plans and track project progress
- Support the building of prototypes to demonstrate and test new concepts and product improvements
- Develop test methods and test plans to assure design quality, including bench testing and pre-clinical study design, implementation, and reporting
- Support design control activities and processes, such as generation of product design documentation for the design history file
- Work with Regulatory to translate results into regulatory submissions as appropriate
- Work with Manufacturing to transfer design into manufacturing process
- Provide post-market support of commercialized products, such as updates to marketing materials