



Senior Technical Project Manager

Overview:

Reporting to the Chief Product Officer, the Senior Technical Project Manager will be responsible for managing the product development lifecycle of disposable IVUS catheters overseeing design for manufacturability with a contract manufacturer (CM) through design freeze, verification, validation, manufacturing scale up, and commercialization.

Educational Requirements:

BS in Mechanical Engineering, Biomedical Engineering, Industrial Engineering, Materials Engineering, Manufacturing, or equivalent technical field. Advanced degree preferred.

Skills/Experience

- 7+ years of hands-on medical device industry experience, with catheter experience preferred.
- Prior experience demonstrating ability to lead product development teams and outside resources such as CMs and meet device design control requirements through regulatory approval.
- Knowledge of global standards and regulations for design controls, risk management, and electrical safety.

Roles and Responsibilities

- Lead effective communications between CM and Evident Vascular to deliver product on time per cost targets using appropriate tools
- Update management stakeholders and coordinate interactions between functional groups such as hardware, software, systems, quality, and regulatory to ensure product technical accuracy, compliance per design controls, and execution per business needs
- Ensure documentation including DHFs (design history files) and DMRs (device master records) is accurate and updated throughout the product development process
- Oversee resolution of technical issues and support proper oversight of suppliers
- Lead cross-disciplinary technical design reviews and participate in product development project phase reviews
- Manage, coordinate, and participate in preclinical studies to ensure requirements are met and user needs are satisfied
- Participate in meetings with key opinion leaders and physician advisors to understand and evaluate user needs and shared product prototypes, and ensure that feedback is properly reflected by the product development team.
- Work with Quality to ensure that risk management requirements are met.
- Develop test plans, protocols, and reports coordinated with CM

Pay range in California, United States

Exact compensation may vary based on skills, experience, and location. Base salary: \$170,000-\$230,000



Note:

This job description in no way states or implies that these are the only duties to be performed by the employee(s) incumbent in this position. Employees will be required to follow any other job-related instructions and to perform any other job-related duties requested by any person authorized to give instructions or assignments. All duties and responsibilities are essential functions and requirements and are subject to possible modification to reasonably accommodate individuals with disabilities. To perform this job successfully, the incumbents will possess the skills, aptitudes, and abilities to perform each duty proficiently. Some requirements may exclude individuals who pose a direct threat or significant risk to the health or safety of themselves or others. The requirements listed in this document are the minimum levels of knowledge, skills, or abilities.

Please reach out to info@evidentvascular.com if you're interested in learning more about this position.