

SOFTWARE TEST ENGINEER

JOB DESCRIPTION

POSITION SUMMARY

The **Software Test Engineer** will lead and prepare verification and validation (V&V) test plans, implement test procedures, conduct hardware and software V&V testing, and complete & finalize test reports for Simpson Interventions products. This position is a key contributing R&D team member with potential for growth. Responsible for organizing highly complex software test programs for the design, development, implementation, and maintenance of software engineering projects. The position also requires the team member to acquire operational working knowledge and know-how in design controls, risk management and participation/support in preclinical & clinical development including regulatory submissions.

ESSENTIAL DUTIES AND RESPONSIBILITIES

The essential functions include, but are not limited to the following:

- Lead and prepare verification and validation test plans, test procedures and test reports
- Participate in the development of market requirements and product specifications, including authoring software requirements and specifications
- Conduct hardware and software verification and validation testing
- Have expertise in and working knowledge with configuration management tools including their oversight and maintenance throughout the development process
- Work closely with cross-functional R&D team to understand system requirements with focus on user experience and clinical usability (UI/UX).
- Ensure all subsystems and products are fully tested in accordance with the product development process including requirements definition, verification, and validation.
- Evaluate all levels of software implementation including operating system, embedded and application software, device drivers and firmware and report findings to responsible team member(s)
- Ensure proper documentation and traceability between system requirements, software requirements, software design and test cases
- Contribute to preparing and writing regulatory subsections or modules for regulatory submissions
- Participate in code reviews, software module tests, software technical reviews and software development phase reviews
- Participate in product design review, risk management and project status update meetings
- Document all relevant R&D activities and results in Company's issued notebook. Wherever relevant, initiate or write standard operating procedures, software specifications, etc.
- Contribute to evaluating and improving software performance; support transitioning investigational device through product development to manufacturing/production and post market lifecycle management
- Contribute to Company's intellectual properties by participating in writing and reviewing of invention disclosures and patent applications whenever necessary.
- Perform other technical tasks or other work-related duties as assigned

MINIMUM QUALIFICATIONS (KNOWLEDGE, SKILLS, AND ABILITIES)

- Minimum Bachelor's degree in Computer Science, Electrical Engineering or Computer Engineering
- Minimum of 5-10 years of related experience
- Expertise in programming languages including C, C++, Python and assembly
- Experience with software verification & validation and lifecycle processes for medical device
- Working knowledge of hardware and software cybersecurity requirements
- Experience with medical device regulations and standards (21CFR820, 21CFR11, IEC62304, IEC60601, etc.)
- Prior experience in cardiovascular or interventional cardiology experience a plus
- Other skills:
 - Advanced problem-solving, organizational, analytical and critical thinking skills, with strict attention to detail
 - Ability to work on unusually complex technical problems and provide solutions which are highly innovative and creative, compare and evaluate possible courses of action after considering various possibilities, and make decisions in the face of different alternatives and without formulas or guidelines, or with guidelines that are not complete and exhaustive
 - Ability to develop expertise or recognized as an expert in a technical area, and maintain technical know-how, looking ahead to identify technical gaps and taking action to address them
 - Ability to work independently and meet development schedule without close supervision; work is generally self-guided with adherence to established patterns and practices
 - Ability to translate complex and technical information to all levels of the organizations, communicate and recommend course of action after considering potential risks of alternatives
 - Excellent documentation and communication skills and interpersonal relationship skills including negotiating and relationship management skills
 - Ability to interact professionally at all organizational levels
 - Ability to manage competing priorities in a fast-paced environment
 - Acceptance to be overseen by managers and more senior team members
 - Ability and willingness to supervise others in resolving complex issues in specialized area based on existing solutions and procedures
 - Ability to provide guidance for the successful completion of major programs and may function in a project leadership role