SENIOR DESIGN ASSURANCE ENGINEER

St. Jude Medical develops medical technology and services that focus on putting more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide. The company is dedicated to reducing risk wherever possible and contributing to successful outcomes for every patient. St. Jude Medical is headquartered in St. Paul, MN and has four major focus areas that include: cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation. For more information, visit sjm.com.

The **Senior Design Assurance Engineer** collaborates with research & development engineering during new product start-ups and establishes checkpoints for testing new products and processes. The Senior DA Engineer is required to establish and ensure compliance with the quality system. This role also monitors regulatory compliance and quality assurance efforts to ensure that our processes conform to quality standards.

Responsibilities:

- Ensure company's adherence to the established Quality System and GMP/ISO standards, including ongoing establishment and improvement to the quality system
- Manage new product Design History Files
- Work with Engineering, Marketing, Manufacturing and Regulatory to establish measurable, valid product requirements
- Aide in definition of test equipment as required to accomplish quality responsibilities
- Develops and documents test plan protocols, test procedures, and test reports
- Perform tests according to various protocol requirements
- Lead completion of risk management and risk analysis including FMEA
- Devise design verification and design validation plans for products based on performance specifications and risk analysis
- Analyze and communicate conformance to specifications and standards
- Conducts technical and statistical investigations concerning compliance to specification and optimization of design relevant to specification
- Lead in definition and completion of in vitro testing including applicable animal studies
- Lead in defining and measuring process capability, process controls, and process validation
- Lead in definition and measurement of CTQ parameters

Required Qualifications:

- Bachelor level degree in Engineering or Technical Field
- 5-8 years design assurance experience including prior medical device experience
- Previous Quality engineering experience and demonstrated use of Quality tools/methodologies
- Detailed knowledge of FDA, GMP, and ISO 13485
- Solid communication and interpersonal skills
- Project management and leadership skills, including the demonstrated ability to lead multi-departmental project teams and resolve quality-related issues in a timely and effective manner Advanced computer skills, including statistical/data analysis and report writing

Preferred Qualifications:

- Advanced degree
- ASQ CQE certification
- Design for Six Sigma and Critical to Quality training and experience

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