

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 **Quality Engineer II** is responsible for developing and maintaining quality engineering methodologies and providing quality engineering support within manufacturing.

Responsibilities:

- Identify and implement effective process control systems to support the development, qualification, and on-going manufacturing of products to meet or exceed internal and external requirements
- Lead in the implementation of assurances, process controls, and CAPA systems designed to meet or exceed internal and external requirements
- Assist in the development and execution of streamlined business systems which effectively identify and resolve quality issues
- Apply sound, systematic problem-solving methodologies in identifying, prioritizing, communicating, and resolving quality issues
- Design and conduct experiments for process optimization and/or improvement
- Appropriately document experiment plans and results, including protocol writing and reports
- Lead process control and monitoring of CTQ parameters and specifications
- Lead and implement various product and process improvement methodologies (e.g., Six Sigma and Lean Manufacturing)
- Lead the investigation, resolution and prevention of product and process nonconformances
- Participate in or lead teams in supporting quality disciplines, decisions, and practices (e.g., represent the Quality function as a Core Team Member)
- Lead in the completion and maintenance of risk analysis
- Work with design engineering in the completion of product verification and validation
- Work with microbiology to ensure appropriate environmental monitoring and that microbiology requirements are considered in product and process development activities

Qualifications:

- BS degree in Engineering; advanced degree preferred
- 2-5 years experience
- Engineering experience and demonstrated use of Quality tools/methodologies
- Detailed knowledge of FDA, GMP, ISO 13485, and ISO 14971
- 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 skills
- Prior medical device experience preferred
- Experience implementing various product and process improvement methodologies (e.g., Six Sigma and Lean Manufacturing)
- ASQ CQE or other certifications preferred

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