Quality Engineer II

(Requisition 4000-03)

POSITION SUMMARY: Provide quality engineering support in the manufacturing of SSMP products to ensure that the products conforms to established specifications and consistently meet or exceed the requirements of our customer and patients.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Assist in the development and implementation of Second Sight's Supplier Evaluation Program; address problems and recommend solutions to supplier quality; interface with suppliers to ensure product specifications are met.
- Provide support for incoming and in-process Quality Control activities including appropriate selection and use of measurement tools and knowledge of Smartscope programming & operation.
- Create and revise Quality Control procedures for incoming and in-process inspection.
- Perform product release
- Support manufacturing line (process validation, equipment validation, etc.)
- Participate in Material Review Board. Review and approve the disposition of non-conforming product.
- Provide technical guidance on the use of Quality Engineering methods and tools for identifying and resolving quality issues.
- Develop data collection processes and reports regarding performance of the manufacturing operation and Quality Management system as directed by management.
- Identify non-conformance trends and opportunities for quality improvements. Proactively investigate and implement quality engineering practices to resolve non conformances and quality issues.
- Implement or lead the implementation of quality initiatives to support the departmental and company goals and priorities.

EDUCATION/CERTIFICATION: BS degree in Engineering or related discipline preferably with Master in related engineering field.

EXPERIENCE REQUIRED: 3 or more years experience as a Quality Engineer or in related field in the medical device industry. ASQC CQE a plus. Or equivalent combination of education and experience.

REQUIRED KNOWLEDGE:

- Applies regulatory requirements such as FDA QSR, European Active Implant Medical Device Directive and other regulatory requirements. Generate procedures in compliance with regulations.
- Have knowledge of statistical techniques and quality tools with proper application of these techniques.
- Ability to apply ISO/EN Sterilization and Biocompatibility standards and guidelines

SKILLS/ABILITIES:

- Excellent people skills, team oriented
- Excellent problem-solving skills
- Effective written and verbal communication and organizational skills
- Be able to coach others or teach the proper use of quality tools and problem solving techniques.