

Senior Quality Engineer

POSITION SUMMARY: Develops, implements and maintains quality engineering methodologies, systems and practices which meet Second Sight quality and regulatory requirements. Provide quality engineering support in the design, development, manufacture and servicing of SSMP products to ensure that the products conform to established specifications and consistently meet or exceed the requirements of our customer and patients.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Implement or lead the implementation of quality initiatives to support the departmental and company goals and priorities.
- Identifies and implements quality/process control system to support the development, qualification and ramp-up manufacturing of devices.
- Lead in the implementation of the CAPA, process controls and quality assurance system
- Provide technical guidance on the use of Quality Engineering methods and tools for identifying and resolving quality issues.
- Participate in Material Review Board. Review and approve the disposition of non-conforming product.
- Identify non-conformance trends and opportunities for quality improvements. Proactively investigate and implement quality engineering practices to resolve non-conformances and quality issues.
- Perform product release and support manufacturing line (process validation, equipment validation, etc.)

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

EXPERIENCE REQUIRED:

- 5-8 years experience as a Quality Engineer or in related field in the medical device industry.
- ASQC CQE a plus.

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.
- 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.