QUALITY ASSURANCE ENGINEER

Develops, implements, and maintains Quality Engineering methodologies, systems and practices. Provide Quality Engineering support in the design, development, manufacture and servicing of implantable medical devices to ensure that the products conforms to established specifications and consistently meet or exceed the requirements of our customers, patients and regulatory agencies. Conducts and/or facilitates internal Quality System Audits.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Plan and conducts internal audit of specific processes or areas to an approved schedule to ensure elements of the QMS are functioning as intended. Tracks and verifies corrections and Corrective actions are appropriately implemented.

- Provide quality engineering support to manufacturing. Lead in the implementation of quality systems, process controls and corrective action systems to meet Quality policy and external requirements to ensure safe and effective products are developed and produced. Identifies and implements quality/process control system to support the development, qualification and ramp-up manufacturing of devices.

- Work with manufacturing engineering to develop master validation plan, process validation protocols and assure correct execution of the process validation activities.

- Provide quality engineering support to the product development team. Identify and implement the quality engineering deliverables per Second Sight's Design Control policy to ensure that the specified design requirements are met. Work with project team to develop and review design verification and validation protocols/reports.

- Participate in Material Review Board. Identify non-conformance trends and lead the investigation to solve the problem. Identify non-conforming trends, prepare Quality metrics periodic reports and develop investigation plans if applicable. Review and approve the disposition of non-conforming product.

- Assist in the development and assessment of Second Sight's Supplier Evaluation Program; address problems and recommend solutions to supplier quality; interface sufficiently to ensure product specifications are met at supplier.

- Review document control changes to products, process, software and other changes for reliability/quality impact.

- Assist with the Calibration and Preventive Maintenance of equipment in compliance with Second Sight's Standard Operating Procedures. Develop calibration methods and frequency for new gauges and equipment.

- Lead in the implementation of quality engineering practices, process controls and CAPA system to meet or exceed product and system requirements. Assist in the implementation of SSMP Document Control Policies and procedures.

- Review and approve lot history records to ensure product compliance with specifications and regulatory requirements.

QUALIFICATIONS:

EDUCATION: Bachelor's Degree (or higher) in Engineering Science or related field. Related professional experience may be considered in lieu of education.

EXPERIENCE REQUIRED: Requires 3-5 years' medical device experience, or highly regulated industry, with working knowledge of quality systems requirements. Higher education in related discipline may be considered in lieu of experience.

REQUIRED KNOWLEDGE:

- Ability to read, understand and execute quality procedures.
- Knowledgeable of GMP and ISO requirements.
- Knowledgeable with the principles of root cause analyses, validation and verification.
- Good interpersonal skills.
- Effective written and oral communication skills.
- Computer skills - proficient in web-based applications, spreadsheet, word processing
- Working knowledge of risk management desirable.

SKILLS / ABILITIES:

- Excellent people skills, team oriented
- Effective written and verbal communication and organizational skills