POSITION DESCRIPTION

Position Title: Sr. Document Control Analyst **Department:** Quality

Name of Incumbent: **Supervisor:** QA Manager

Date of Hire: **FLSA Status:**

OVERVIEW OF POSITION:

Provide quality systems expertise to ensure adherence to regulations, company policies, and internal procedures in all phases of product life cycle with particular focus on documentation and configuration management, quality record archival and maintenance, employee training, quality system integration, and external standards.

DUTIES AND RESPONSIBILITIES:

- Administer, improve, and maintain the company's Document Control and Training Management Systems. Lead integration of documentation and record control systems into quality management software modules
- Create and maintain all controlled document files, both hard copy and electronic versions, including associated logs. Maintain security controls on all documents
- Manage and track quality system employee training program
- Manage documentation revision related to reviewing and writing policies, procedures, assembly instructions, and other controlled documents
- Review manufacturing documentation of in-process work, incoming materials, and finished goods in the manufacture of medical devices
- Collect and trend quality metrics in the areas of document change requests, training compliance, etc. in support of Management Review meetings
- Create quality reports and make recommendations for improved reporting
- Audit quality records
- Train staff on proper procedures and document policies as needed
- Adhere to general safety rules, manufacturing procedures, company policies and procedures, Good Manufacturing Practices, ISO / MDD, and FDA regulations
- Complete projects consistent with corporate objectives

- Support company goals and objectives, policies and procedures, Good Manufacturing Practices, ISO/MDD and FDA regulations
- Perform internal quality audit activities and ensure proper follow-up/closure
- Lead or participate in quality system improvement projects and corrective actions, as required.
- Train field employees to the radiation exposure program and manage field personnel's radiation badges.
- Support supplier quality programs both internally and with local on-site audits, as needed
- Provide support for ISO and FDA audits
- Work overtime, as necessary
- Perform other duties, as assigned

MINIMUM EDUCATION REQUIREMENTS:

High school diploma is required. Bachelor's Degree is preferred. In the absence a Bachelor's Degree, related experience may substitute.

MINIMUM EXPERIENCE REQUIREMENTS:

Minimum of five to seven years of medical device quality system experience as well as MDD/ ISO 13485 and/ or GMP System experience or equivalent. ERP System (e.g. IQMS) experience preferred, but not required.

OTHER NECESSARY QUALIFICATIONS:

- ISO 13485 Quality System Training
- ISO 13485 Lead Auditor Training (desired)
- Strong organizational skills.
- Strong communication skills, both verbal and written.
- Good computer skills including word processing and spreadsheets.
- Ability to utilize basic math skills.