Position Title: Quality Engineer
Functional Group: Quality Assurance, Production, Materials, Manufacture Engineering
Report To: VP of Quality Assurance

PURPOSE OF POSITION: The Quality Engineer will be responsible for creating, updating, and maintaining quality system documents and records. The position will be expected to review, approve, and implement changes to quality system records produced by document control, material control, product development, production, and incoming inspection.

MAJOR DUTIES AND RESPONSIBILITIES:
- Trains and supports all associates on product processes and procedures.
- Proactively report project activities, issues, and schedule to management.
- Control of quality system records, revisions, including accurate and timely storage/retrieval.
- Control of the distribution and accuracy of all the documents used in Product Development, Production, and Quality Assurance.
- Supervises Quality Control and Production personnel data collection and entry into Quality System reports.
- Assist in the writing and execution of qualification procedures for tools and fixtures used in manufacturing.
- Supervises the timely processing of complaints, nonconformity (MRR), returned goods and Corrective and Preventive Action (CAPA) activities including the processing, database management and data trending.
- Supervise incoming inspection, finish good inspections and final product release for distribution.
- Display working knowledge of the proper use of hand tools, simple power tools, and basic electronics.
- Provide feedback and verification of assembly and process testing procedures.
- Perform occasional lifting of up to 50 pounds for inventory and equipment relocation.

EDUCATION / EXPERIENCE REQUIREMENTS:
- Preferred undergraduate degree or related degree required in related discipline industry experience.
- Minimum of 5 years combined experience in medical device quality and regulatory systems.

OTHER QUALIFICATIONS:
- Experience working within medical device quality systems including Quality System Regulation (QSR) and ISO 13485:2016.
- Knowledge of and/or experience with the Medical Device Directive desirable.
- Must be detail oriented, an effective communicator, and able to lead members of multiple disciplines within a team environment.
- Good technical writing skills.
- Strong computer skills, including Word and Excel
- Detail-oriented and strong organization skills

Associate Signature	Date Reviewed
Management Signature	Date Reviewed