Quality Specialist II

POSITION REPORTS TO: Sr. Director of Quality Assurance

POSITION SUMMARY: Under minimal supervision, responsible for general administration and maintenance of SSMP documents and QA records per document control and quality records procedures including processing of change request, document control review and release of approved documents. Responsible for coordinating SSMP training activities. In addition, may be required to perform inspection, compile and issue quality reports, assist in administration of the Quality Management System (QMS) software.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Responsible for the document control process, review and process change request for completeness, perform document control review of draft documents for proper format and completeness, release approved documents
- Maintain all QA quality system records per company SOP such as audit records, environmental testing records, document control hard copy file legacy documents etc.
- Assist with external audits, in charge of running the back-room and compiling documents for the audit
- Assist/may perform internal audits for SSMP.
- Responsible for maintaining the records room.
- Assist in the Calibration program by reviewing and approving calibration documents for quality.
- Maintain and control the distribution of external standards
- Input and maintain the Training requirements of all employees, maintain training records, and coordinate course training with trainer.
- May also be involved in label inspection, catalog item receiving inspection approval, DHR review and QC inspection of components and products.
- Assist QE in the collection and monitoring of quality data. This will include the preparation and distribution of Open NCMRs, Open CAPAs, complaint metrics and QA hold inventory.

EDUCATION/CERTIFICATION: High School Diploma or equivalent. AA degree is preferred

EXPERIENCE REQUIRED:

- Must have at least 5 years clerical/computer related experience or equivalent combination of education and experience.
- At least three years of Document Control experience in the regulated industry with at least one year in administration of QMS software.

REQUIRED KNOWLEDGE:

- Must have an understanding of FDA QSR and European AIMDD directives and other regulatory requirements
- Basic knowledge of record keeping

SKILLS/ABILITIES:

- Ability to work independently under minimal supervision
- Must be experienced in the use of MS Office, particularly Word and Excel and internet search.
- Excellent people skills, team oriented