



Title: Document Control Clerk
Reports to: Regulatory Affairs Manger
Status: Non Exempt

Summary of Position

The Document Control Clerk is responsible for the smooth and efficient flow, safe keeping and integrity of all Quality System documents used throughout the company.

Essential Job Functions

- Examine documents to verify compliance, completeness and accuracy of data
- Confer with document originator and approvers to resolve discrepancies and apply required changes to documents
- Releases new, changes existing, obsoletes old, distributes copies of controlled documents
- Controls document control Master List, Work Instructions, Forms, Quality System Procedures while maintaining all Tables of Contents and Distribution Lists.
- Assigns Document Numbers for all Quality System Documents
- Assigns numbers for all DCO's, RIR's, DIF's and CAPA numbers when requested by employees
- Updates Routing sheet when document packets come through
- Maintains Employee Training Records
- Assist with Internal and External Audits
- Files documents when closed as needed
- Creates Product labels in database
- Maintains minutes from Management Review Meetings, and other meetings when necessary
- Assists in developing submissions to regulatory agencies

Essential Job Requirements

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Experience

- 3 years document control experience required
- Experience in Medical Device and/or FDA regulated industry preferred

Required Skills

- Excellent organization and record keeping skills
- Excellent verbal and written communication skills
- Ability to manage multiple priorities with expected timelines
- Proficient computer skills as related to document control including Excel and Word
- Ability to interface with all levels of the company

Physical Requirements / Working Environment and Conditions

- Ability to work in a moderately noisy environment

- Ability to maintain a high level of concentration while ensuring that all aspects of document controls are completed
- Ability to utilize necessary office equipment, computer software, hardware and equipment
- Ability to perform the following physical activities; stooping, reaching, sitting, standing, walking, feeling, talking and hearing.

Education

- High School Diploma or equivalent required, Bachelors Degree preferred

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