JOB DESCRIPTION

Position Title: Document Control Specialist III

Reports to: Quality Supervisor

Department: Quality

FLSA Status: Non-Exempt

PURPOSE OF JOB:

Develop, coordinate, and maintain the company's Document Control and Training systems, and provide administrative support for the Company's Quality System.

MAJOR DUTIES AND RESPONSIBILITIES:

- Process Change Orders (COs) in a timely manner with high level of accuracy.
- Ensure compliance with controlled document format and content.
- Maintain Document Control and Quality System related databases and logs (e.g. issuance of part/document numbers, laboratory notebooks).
- Distribution of controlled documents and retrieval of obsolete/superseded documents.
- Periodically inspect/audit controlled binders to ensure accurate distribution (i.e. correct documents and current revisions).
- Maintenance of training records and training database, run reports and communicate training gaps to department supervisor.
- Maintain external standards library including ordering and tracking through internet based services.
- Scanning, filing and maintenance of all types of quality system records.
- Proactively champion document control system improvements and resolution of issues.
- Train and assist users of Document Control, Change Order and Training systems.
- Report monthly document control metrics to management.
- Assist in the validation and maintenance of quality system modules as assigned.
- Perform other Quality System related duties as assigned.

EDUCATION REQUIREMENTS:

- Bachelor's degree or equivalent industry experience with associate degree preferred.
- Certified Quality Improvement Associate preferred.

EXPERIENCE REQUIREMENTS:

- Minimum 6 years of experience in Document Control or similar Quality Systems or related role with at least 3 years in medical device, pharmaceutical, or related industry.

This job description is not all inclusive. Incumbents may be required to complete other miscellaneous responsibilities as required.

OTHER QUALIFICATIONS:

- Certified Quality Improvement Associate preferred.
- Must be proficient with WORD, Excel, Power Point and Adobe.
- Must be organized and have strong attention to detail.
- Excellent communication and time management skills required.
- Ability to work independently and prioritize tasks in a fast paced and dynamic environment.
- Knowledge of FDA QSR/cGMP, ISO 13485 and MDD regulations is required.
- Proficiency with SolidWorks and Electronic Document Management systems preferred.

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