

DOCUMENT CONTROL SPECIALIST

SUMMARY: Responsible for general administration and maintenance of company documents and QA record per document control and quality records procedures including processing change requests, document control review and release of approved documents. Responsible for coordinating training activities in EtQ. May be required to perform inspection, compile and issue quality reports and assist in EtQ web administration.

ESSENTIAL DUTIES & RESPONSIBILITIES:

- Review and process change request for completeness, perform document control review of draft documents for proper format and completeness and release approved documents.
- Maintain all QA system records such as audit records, environmental testing records, document control hard copy and file legacy documents.
- Assist in the calibration program by maintaining the master calibration list of gauges requiring calibration.
- Maintain and control the distribution of external standards.
- Input and maintain the training requirements of all employees, maintain training records in EtQ Training Module and coordinate course training with trainer acting as “training coordinator”.
- May participate 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 includes the preparation and distribution of Open NCMRs, Open CAPAs, complaint metrics and QA hold inventory.
- Perform web administration tasks in EtQ such as reassignment of documents, NCMRs, etc.

QUALIFICATIONS:

Education:

- High School or equivalent
- AA preferred

Experience:

- Must have at least 5 years clerical/computer related experience or combination of education and industry experience.
- At least 2 years Document Control experience in a regulated industry with at least one year EtQ or similar document control system.

Required Knowledge:

- Must understand regulatory requirements such as FDA, QSR and European AIMDD directives.
- Basic knowledge of record keeping.
- 55 wpm typing
- Experience with MS Office, particularly Word, Excel and internet searching
- Team oriented with excellent people skills