

JOB DESCRIPTION

Title: Document Control Specialist
Department: Quality
Reports To: Quality System Manager
FLSA Status: Exempt
Survey Job Code: 6251 – 6256E
Survey Job Title: Document Control Specialist

Summary:

Coordinates, implements, and maintains the company's Document Control and Training System. Coordinates labeling activities through change management interfacing with suppliers to meet quality standards and timelines. Strictly follows established procedures and policies needed to meet the demands of document control in a regulated medical device company.

Essential Duties and Responsibilities:

- Responsible for overall coordination of controlled documentation within the company.
- Performs the Document Control function within the validated MasterControl system.
- Coordinates and chairs Change Control Board meetings.
- Orders external standards and maintains tracking system.
- Assist in supporting external audits, coordinating activities in backroom and ensuring timely response to documentation requests for auditors.
- Supports user requests for documentation and trains users in MasterControl.
- Supports change management of labeling and ensures accurate completion of Labeling Verification form.
- Performs self audits of satellite DMR locations and ensures that the current revision is available in a timely manner.
- Administers training system in MasterControl, setting up users and exams as required.
- Maintains quality records per applicable SOPs.
- Investigates and responds to corrective actions related to Document Control, Training and External Standards.
- Responsible for coordinating document change orders (DCO), facilitates review, approval, and retention of Risk Management documents.
- Other duties may be assigned as deemed necessary by the supervisor.

Education, Training, Skills and Experience Requirements:

- Minimum of 2 to 5 years document control experience in the Medical Device industry.
- Experience with electronic document control and training system preferred.
- Knowledge and experience with CE marking, labeling standards and practices is desirable.
- Exercises judgment within broadly defined practices and policies in selecting methods, techniques and evaluation criteria for obtaining results
- Strong verbal, written, organizational, time management and interpersonal skills.
- Strong computer skills, including working knowledge of MS Office and e-mail.

Physical Demands:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. While performing the duties of this job, the employee is regularly required to stand; walk, and sit for extended periods of time.

Print Name

Employee Signature

Date