







Job Description

Work Location: Plymouth, MN

Assignment Duration: Through March 2015

Summary of Position:

The Senior Technical Communication Specialist position will work with minimal direction and supervision within the Peripheral Vascular group to create and update Instructions For Use (IFU), coordinate translations, author ECOs, complete proof approvals, and ensure final product labeling meets regulatory standards, as well as on-time delivery, within the defined project schedule(s).

Responsibilities:

- Leads the process of creating and updating IFUs for assigned product labeling projects, in
 multilingual and supplemental formats. Works with engineering, marketing, clinical,
 regulatory, and quality, etc., to develop content. Schedules and attends project meetings
 and meets with individual subject matter experts, as necessary.
- · Creates a variety of IFU layouts and paragraph styles using Adobe InDesign.
- Collaborates with package engineering to provide sample IFU layouts for validation step and determine material specification requirements.
- Coordinates translations: interfaces with translation vendor, obtains quotes, performs
 quality check on returned files, releases in document control system to meet project
 schedule.
- Enhances readability of product IFUs by editing for grammar, consistency, style, and format, to comply with style guide and corporate marketing requirements.
- Assists regulatory with the preparation of IFUs for submissions and clinical data updates.
- Coordinates with labeling team to ensure product labeling content aligns across all components.
- Works closely with project managers, package engineers, label specialists, graphic
 designers, artwork coordinators, and CAD designers to coordinate all aspects of the
 Covidien brand and ensure a timely release of final labeling.
- Authors ECOs (electronic change orders) for all IFU changes and obtains cross functional approvals to release final labeling in the document control system (MatrixOne).
- Work with planning to determine disposition of IFU revision changes, as necessary.
- Coordinates IFU implementation to ensure that all requirements and deadlines are met, including: translation, graphic design, documentation release, and vendor proof approvals.
- Interfaces with print vendors and purchasing to ensure correct source files are delivered to vendor and proofs are ordered on a timely basis. Completes IFU proof approval process for first article using a red overlay.
- Maintains current status of supplemental IFU matrix and releases in document control system.
- Maintains consistent source file management and organization; archives history files as necessary.
- Exercises planning and problem solving skills in various situations.
- Mentors and trains other Technical Communication Specialists, as necessary.
- Provides feedback on procedures and suggestions for continuous process improvements.
- May assist with the rebranding project and label artwork using Adobe InDesign.
- May be required to perform other duties as assigned.

Job Requirements

Required Qualifications:

- · Bachelor's degree required
- Minimum 5 years technical writing experiencing in the medical device industry, with

familiarity of medical device labeling and harmonized standards, or a minimum of 7 years general technical writing experience

- Experienced with Adobe InDesign
- ECO experience using sound revision control processes, preferably in a medical device environment
- Strong communication and writing skills
- Good interpersonal skills and the ability to perform effectively in a fast paced environment.
- Excellent organizational and time management skills
- Excellent problem solving skills
- Ability to work with cross-functional project teams
- o Ability to coordinate multiple tasks, and manage priorities

Preferred Qualifications:

- Background in a quality systems environment is a plus.
- Experience with Adobe Creative Suite, WorldServer, MatrixOne, or Agile, is a plus.

^{**}Interested candidates should email a resume to hr@jpgassoc.com



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