



Job Description – Senior Labeling Specialist

Reports To – Director, Project Management

Job Responsibilities

This Specialist will manage all medical device and package labeling in accordance with FDA Regulations, EUMDR, ISO requirements and Standard Company Operation Procedures.

General Description and Duties:

Key responsibilities:

- Maintain Instructions for Use documents, product labels and packaging labels in compliance with regulatory standards as well as internal labeling requirements.
- Work with multi-functional team (engineering, marketing, manufacturing, regulatory, legal) to facilitate completion of labeling and artwork assignments.
- Manage and support UDI implementation.
- Manage prepress activities necessary to prepare labeling artwork files for accurate output.
- Partner with vendors for translation projects. Identify translation issues and determine resolutions.
- Coordinate between print house and translation house.
- Proofread labeling artworks to ensure content meets label specifications.
- Support production team in labeling execution and labeling inventory management.
- Manage update of online IFUs.
- Provide input to Quality team for labeling SOPs.

Projects and Other Duties:

- Most work is highly independent and collaborative in nature.
- Execute strategic initiatives related to labeling.
- Responsible for training others in subjects related to product labeling.
- Serve as a point person for project teams for labeling changes.

Position Qualifications

- Bachelor's degree in a technical field.
- At least 3 years of work experience in medical device industry.
- At least 1 year experience in managing or supporting labeling projects in medical device industry.
- Microsoft Office proficiency (Outlook, Word, Excel, PowerPoint).
- Understanding of regulatory standards.
- Clear and effective verbal and written communication skills.
- Attention to detail and organizational skills.

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- Ability to work in a fast-paced team environment.
 - Technical writing skills preferred.
 - Project management experience preferred.
 - Working knowledge of Adobe InDesign preferred.

Minimum Education:

- Bachelor's degree in technical field.

Minimum Experience:

- At least 1 year experience in managing or supporting labeling projects in medical device industry.