Regulatory Affairs/Quality Assurance Specialist

Job Description:

The Regulatory Affairs/Quality Assurance Specialist works closely with members of the RA/QA team to ensure compliance with company SOPs as well as national and international regulatory requirements. The individual may assist in the registration of products by preparing and submitting documentation needed for registration worldwide. Job is at our headquarters in Addison, TX. Please apply only if you live in the Dallas/Fort Worth Area.

Duties and Responsibilities:

- Create and/or revise quality system procedures and work instructions.
- Assist with regulatory submission preparation and submission.
- Maintain annual medical device registrations and ensure product listing updates.
- Assist in reviewing changes to existing products to define requirements for regulatory submissions.
- Provide regulatory reviews of customer complaints and define the regulatory reporting requirements.
- Maintain current knowledge of FDA and international regulations, guidance and standards applicable to our products.
- Work with cross-functional teams including Engineering, Marketing, Operations and Manufacturing to provide guidance to ensure compliance with regulatory requirements and internal SOPs.
- Provide work direction and guidance to peers.
- Assist in conducting internal audits.
- Serve as the caretaker for all controlled documents by managing the routing, review, distribution and archival of new and revised controlled documents.
- Support supplier qualification and management activities.
- Maintain annual licenses, registrations, listing and patent information.
- Provide regulatory input for recall communications.
- Ensure product safety issues are reported to regulatory authorities.
- Support CAPA management
- Other duties as assigned.

Qualifications/Skills

- Bachelor's Degree and at least two years' experience in a regulatory affairs/quality assurance role.
- Medical device industry experience is a plus.
- Working knowledge of US FDA medical device regulations and ISO 13485.
- Strong computer skills including MS Word, PowerPoint and Excel.
- Strong attention to detail, thinks analytically and critically.
- Strong organizational, interpersonal, written and oral communication skills.
- Self-motivated, detail oriented and a team player.

****To apply for this opportunity, please send a resume and cover letter to careers@ctlmed.com, referencing the Regulatory Affairs/Quality Assurance Specialist position.**