Title

Senior Regulatory Affairs Specialist

Status

Full-time

Location Base

Taiwan or China

Department

Quality Management Department

Position Overview

The position's primary responsibility is to plan, organize and implement strategies and activities required to acquire regulatory approval for new and revised product lines in the United States and Europe regions.

Essential Functions

- Participate in the product development team throughout all phases to ensure FDA, CE mark, and other international regulatory requirements are incorporated as part of the development process.
- Evaluate medical device regulations and develop strategies for bringing products to market.
- Assess global impact of changes to launched products and support notifications/submissions as required.
- Author submissions and other regulatory documents to obtain approval in order to enter into the market.
- Review labeling and marketing literature for compliance with regulatory requirements.
- Remain informed regarding new regulations or changes to existing regulations and communicate relevant information to project team and QM team.
- Comply with existing and/or new regulatory requirements as they relate to the Company products and procedures.

Skills & Requirements

- Prefer 5+ years of experience within medical device and/or other regulated industry
- Prefer knowledge in FDA, CE mark, and/or other international regulations
- Obtain solid understanding of the FDA medical device listing and establishment registration process
- Experienced interacting directly with FDA, CE, and Notified Body reviewers/inspectors
- Demonstrate strong interpersonal communication, collaborative team work, and negotiation skills
- Experienced with regulatory requirements for medical devices leading to market approval in the US market
- Able to work independently as well as in a team environment
- Excellent oral and written communication skills
- Must be fluent in Chinese and English
- Willing to travel