



POSITION DESCRIPTION

Senior Regulatory Affairs Specialist

Ascension Orthopedics, Inc.

Submit resume to: resume@ascensionortho.com

Position Summary

This individual will be responsible for development and preparation of foreign and domestic regulatory submissions. Knowledge of ISO 9001 / 46001 and CE Mark certification requirements, 510(k) / PMA / IDE submission requirements, and FDA QSR regulations is required. Demonstrated excellence in technical writing and oral communication skills is required. Experience with orthopedic implants is desirable.

Responsibilities:

1. Research and identify medical device regulatory submission requirements for US and other countries pertinent to product development activities.
2. Review and compile appropriate technical information and clinical data into regulatory submissions and send them to the appropriate regulating authorities.
3. Based upon the available technical information and clinical data, determine additional information needed to complete regulatory submissions. In conjunction with other departments and resources, plan and coordinate the efforts to generate and produce this additional information.
4. In conjunction with marketing and senior management, identify, screen, recommend, and develop appropriate distributor relationships necessary to support marketing applications in various non-US countries.
5. Develop and/or review product labeling for compliance with appropriate medical device standards and regulations, including instructions/information for use, package labeling, surgical technique descriptions, video instruction tapes, and product and company brochures and advertising.
6. Work with quality assurance and other departments to ensure corporate compliance with appropriate regulations prior to and during audits.

Qualifications:

- General:** Able to work full time.
- Education:** BA/BS with at least 2 - 5 years related work experience in the regulatory environment of Class I, II and III medical devices.
- Experience:** Knowledge of ISO 9001 / 46001 and CE Mark certification requirements, 510(k) / PMA / IDE submission requirements, and FDA QSR regulations is required. Experience with medical device implants is a desirable.

Skills: Must have strong interpersonal and technical writing skills, possess multitasking capability and be computer literate.

Job Demands

Job Demands: Office environment. Some travel required.

Physical Demands: May require minimal lifting and carrying of objects.

Environmental Demands: Minimal environmental demands.