

SR. Regulatory Affairs Specialist – International/Spine 2011.142

Resumes should be sent to: careers@osteomed.com

In Subject Line must Reference: (Job Code: 2011.142)

Job Summary: As a core member of the Corporate Compliance Team, the Senior Regulatory Specialist provides timely and valued regulatory guidance (written and / or verbal) by owning the following tasks:

Duties & Essential Job Functions:

- Develop, coordinate and prepare product registration files for submissions in Asia, Canada, EU and other select worldwide locations.
- Participates in direct interaction with regulatory agencies on defined matters
- Collaborate with worldwide colleagues regarding license renewals and updates
- Create and maintain technical files
- Identify potential regulatory approval risks based on changes in regulations, standards and country specific issues or other unique characteristics of the project, as well as regulatory inputs on time to approval/market
- Provide leadership and guidance on global compliance, such as CE Marking and product registrations, clinical evaluations in accordance with MDD Annex X & ISO 13485, Canadian CMDCAS, etc.
- Coordinate Annual Standards review with OsteoMed technical staff
- Coordinate translations of product labeling to support international registrations/marketing
- Support audits by international 3rd parties (e.g., TUV, ANVISA) as required
- Review and approve advertising, promotional items and labeling for international regulatory compliance.
- Provide work direction/guidance as needed to other specialists or associates
- Other responsibilities as required and/or assigned

Experience/Skills Required:

- Minimum 5 years of regulatory approvals and submittal work experience (EU MDD, Health Canada, etc.)
- Strong working knowledge of domestic and international Medical Device Regulations, including QSR, MDR, ISO 13485 and European medical directives
- Minimum 5 years of regulatory approvals and submittal work experience (successful 510(k) applications, PMA/IDE experience preferred)
- Experience in FDA guidance documents for Spine products and application of testing standards. Past work experience in orthopedics or spine products preferred
- Requires strong written, oral and interpersonal skills to be able to effectively compose agency submissions and interface interdepartmentally
- Must be able to manage multiple tasks, perform with accuracy and a high attention to detail, and organize and prioritize own work routine to meet established schedule

- Strong experience with the development of device/system risk plan and analyses using processes defined in ISO 14971 and IEC standards/guidelines relating to product safety for medical devices
- Strong Microsoft skills (Excel, Word, Access)

Required Education:

- B.S. or B.A. degree in scientific or technical discipline
- RAC certification - (EU/CAN specialties preferred)

Physical Requirements:

- Lifting requirements- No more than 25 pounds