



Hiring Regulatory Affairs Professionals

Location: Warsaw, Indiana

Sponsorship Available

Relocation Available

Regulatory Affairs Associate, Specialists, Project Managers and Managers

Principal Duties and Responsibilities

- Assist with assembly, distribution, storage and tracking and retrieval of information pertinent to the regulatory process, including the regulatory submissions process. May author and publish electronic submissions.
- Respond to requests from foreign government and/or distributors as needed
- Assist with the research, analysis and communication of information pertaining to the appropriate regulatory pathway for new or modified products
- Provides regulatory direction to development project teams as a core team member; develops regulatory strategy for new products
- Evaluate risk of proposed regulatory strategies; may offer solutions
- Reviews proposed labeling for compliance with applicable global regulations
- Writes and manages the development of package inserts
- Reviews and evaluations promotion and advertising material for compliance with applicable regulations
- Reviews proposed product changes for impact on regulatory status of the product
- Communicates with regulatory and governmental agencies with supervision
- Applies FDA regulations to business practices and provides regulatory input, advice and guidance to design teams

Education/Experience Requirements

- Bachelor's degree (or non-US equivalent) required; concentration in life sciences, technical/engineering or related field, preferred
- A minimum of one year of experience in orthopedic or medical device industry preferred
- A minimum of 3-5 years of experience in Regulatory Affairs, Engineering, Quality, or related field required
- Regulatory Affairs Certification (US or EU) preferred
- A combination of education and experience may be considered

For More Information and to apply

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