



Example of Regulatory Affairs Coordinator Job Description

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Our innovative and growing company is looking to fill the role of regulatory affairs coordinator. Thank you in advance for taking a look at the list of responsibilities and qualifications. We look forward to reviewing your resume.

Responsibilities for regulatory affairs coordinator

- Being the primary point of contact with RA affiliates to contribute to the development and execution local registration strategy and renewals in compliance with relevant laws, regulations and organizational requirements of countries under his/her scope
- Assist the CSS EMEA Regulatory Affairs Manager - EU Strategy in monitoring developments in EU/EMEA legislation and guidelines related to the medical device industry
- Provides analytical and regulatory support to the clinical research support unit
- Supports PI s and study staff by assisting in the data collection and notification required for reporting of Adverse Events Facilitates communication with IRB related to Adverse Events Supports study monitoring, as needed and requested
- Verify and coordinate quality control of submissions proper compliance with department SOPs and Regulatory Authority guidelines
- Coordinate, obtain, legalize, compile and distribute documents needed to support global regulatory submissions
- Prepare, request and track government certifications to ensure smooth transition with registration of new products in global market
- Be responsible for handling various aspects of regulatory compliance activities for commercial health plan business
- Evaluate new state and federal regulations proposed and final state

- Represent RCGA in internal and external implementation processes for the health plan's new and innovative external partnerships

Qualifications for regulatory affairs coordinator

- Knowledge of chemical, microbiological and laboratory testing procedures preferred
- Knowledge of Canadian Medical Device Regulations and Health Canada Federal requirements
- Be persistent and engaged
- Be resourceful skill necessary to solve ongoing issues
- Excellent computer skills and professional demeanor required for interactions with international colleagues and health authority representatives, including a working knowledge of database management proficiency in Microsoft Word, Excel and PowerPoint
- He / She should be computer literate