



Example of Senior Manager, Regulatory Affairs Job Description

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Our company is growing rapidly and is searching for experienced candidates for the position of senior manager, regulatory affairs. We appreciate you taking the time to review the list of qualifications and to apply for the position. If you don't fill all of the qualifications, you may still be considered depending on your level of experience.

Responsibilities for senior manager, regulatory affairs

- Within the framework of Canadian and US Federal regulatory acts, represent CN in discussions and working groups with regulators and railway industry to develop and advance new regulations or carry out modifications to existing regulations which best ensure that CN's interests are protected
- Defines product labeling data requirements
- Responsible for staffing, budgetary management, review process and personnel development and management
- Create and execute the strategies for obtaining new product registrations and supporting the lifecycle management of product portfolio
- Provides regulatory leadership to develop and sustain productive relationships with in-country business partners
- Monitor the external regulatory environmental changes and engage in shaping activities through industry association
- Maintain a positive relationship with health authorities through frequent and transparent dialogue
- Identify and communicate regulatory requirements necessary to perform clinical studies in the assigned markets
- Lead RA team and strengthen talent development for RA staff
- Supports Regulatory Projects Team Leadership on development of regulatory tactics to be communicated to internal stakeholders, GPT as requested

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- Align team members' activities to business goals
 - A minimum of a Bachelor's degree is required, preferably in a Life Sciences related discipline
 - Strong influencing skills to drive accountability of the business to meet its regulatory obligations
 - Enhanced PC knowledge and skill sets utilizing Microsoft Office (Word, Excel, PowerPoint)
 - MS in Regulatory Affairs
 - Experience in business or product management in in vitro diagnostic regulated industry