



Example of Director, Regulatory Affairs Job Description

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Our innovative and growing company is searching for experienced candidates for the position of director, regulatory affairs. To join our growing team, please review the list of responsibilities and qualifications.

Responsibilities for director, regulatory affairs

- Maintain knowledge of global competitive landscape, regulatory environment, regulations and guidelines and keeping management informed
- Maintain regulatory expertise and serve as internal consultant on relevant global regulations and guidelines, current regulatory environment, and regulatory precedent
- Prepare teams for and lead FDA (or other regulatory authority) meetings
- Manage and participate in the creation, review, assembly and submission of regulatory documentation including clinical trial and marketing applications and amendments to these regulatory files, as appropriate
- Support non-program specific projects as assigned such as department initiatives, business development assessments, clinical assessments and department training
- Coordinates submissions to FDA in support of proposed and ongoing development programs (e.g., new IND submissions, IND amendments)
- Ensure AIRM development products comply with regulatory requirements appropriate for each stage of development in both U.S. and globally
- Ensure submissions are done on time, complete and accurate in accordance with regulations and corporate goals
- Ensure proper management of multiple active INDs/CTAs in clinical trials
- Defines the strategic regulatory direction for innovation and portfolio development and global launch excellence for Wave 1 and Wave 2 Markets

- Prior experience with filing CMC sections of the marketing applications is a must
- Be able to effectively work with and influence senior Business Line and Control Function personnel across many business units and countries
- Demonstrate the ability to represent the Bank effectively in dealings with regulators
- Be able to envisage how existing and new technology could be leveraged or employed to enhance compliance processes
- Demonstrate the ability to get things done while ensuring that key stakeholders feel engaged and involved in the successful outcome
- Have strong leadership and interpersonal skills to provide leadership and direction when required, to work independently