



Example of Senior Manager, Regulatory Affairs Job Description

Powered by www.VelvetJobs.com

Our growing company is looking for a 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

- Together with professionals from other departments and in other countries, translating regulations and standards into product requirements
- Reviewing and approving engineering changes, advertising, promotional items and labeling for regulatory compliance
- Represent Merial Regulatory Affairs in Due Diligence visits involving corporate acquisition or merger initiatives (companies and/or products)
- Have accountability for ensuring that Senior Management is aware of any major issues with the project, including any changes to risks, so that appropriate message is communicated on a one single regulatory voice to any key project governance milestone committee
- Interact directly with FDA for each project and ensure that communications from FDA are properly communicated to the business and up through Senior Management
- Coordinate timely dispatch of CTD dossiers components to the FDA, coordinate the responses to FDA questions
- Contribute to regulatory affairs quality and continuous improvement initiatives
- Have responsibility for keeping abreast of regulatory guidance and technical/scientific developments relevant to project
- Manage regulatory aspects of the copy review / approval process for product promotional materials for assigned products, indications, or audiences

Qualifications for senior manager, regulatory affairs

- Generally strong in working well with others and within global teams
- Generally strong and independent skills in the area of regulatory strategy such as understanding broad concepts within regulatory affairs and implications across the organization and globally
- BA/BS Degree, preferably in a health/life sciences or related field
- Minimum of three years of experience (Sr
- Commercial launch and advisory comment process experience preferred
- Must have previous experience in leading Major Health Authority interactions