Example of Senior Manager, Regulatory Affairs Job Description

Our innovative and growing company is looking to fill the role of senior manager, regulatory affairs. Please review the list of responsibilities and qualifications. While this is our ideal list, we will consider candidates that do not necessarily have all of the qualifications, but have sufficient experience and talent.

Responsibilities for senior manager, regulatory affairs

- Directs the development of the regional product label by collaborating with the Labeling Working Group to define commercial objectives in the context of available and expected scientific data, regulatory guidance and precedent
- Consistent with GRT strategy, advise GDT on regulatory implications and requirements related to global clinical development plans and objectives
- May interface between global & regional headquarters to ensure both parties are kept updated on regulatory progress & operational issues
- Lead cross-functional team to develop complex regulatory submissions
- Manage internal personnel and activities of external contractors
- Develop individual talent and coach others to produce results
- Provide regulatory expertise, strategy, and guidance with respect to creation and execution of advertising, promotional and other related materials
- Serve as primary contact with the FDA Office of Prescription Drug Promotion (OPDP) for assigned products
- Review and approve Form FDA-2253 submissions to OPDP
- Represent Merial involving key interactions with multiple trade associations (at various levels) to help incorporate Merial objectives

Qualifications for senior manager, regulatory affairs

- 4-7 years previous pharmaceutical drug development experience

- Ability to lead complex regulatory submissions
- Direct experience in oncology
- BA/BS degree in the life sciences