Example of Manager, Medical Affairs Job Description

Our growing company is looking to fill the role of manager, medical affairs. If you are looking for an exciting place to work, please take a look at the list of qualifications below.

Responsibilities for manager, medical affairs

- Develops, or is responsible for the development of, regulatory solutions to problems of moderate to intermediate complexity that may affect diverse functional areas of the business or company or unusual complexity in the function
- Provides technical guidance and regulatory training/mentoring to other Regulatory Associates and/or cross functional teams
- Represent specific business areas or geographies as the primary contact, interacting and creating an ongoing, proactive relationship and collaboration with internal scientific, marketing, and engineering colleagues and/or regulatory authorities
- Responsible for overseeing regulatory compliance, development and timely national and international regulatory submissions, ensuring that all regulatory activities are conducted with the highest integrity and in an ethical manner
- Reviews staff submissions to identify adequacy of sections, completeness and consistency of story and overall content of submissions, may be responsible for authoring submissions when needed
- Represent departmental function, acting as primary interface with regulators, presenting strategies and negotiating solutions, and may lead and coordinate intra- and inter-company projects
- Interprets, executes, and recommends modifications to operating policies at business level
- Shares experience with most stages of product life cycle and concentrates on new product development and post-market applications of existing products

- Acts as an effective regulatory consultant to management and other functions

Qualifications for manager, medical affairs

- Outstanding record of peer-review publication and demonstrated efficacy in medical and scientific affairs activities as they pertain to molecular diagnostic assays and instrumentation
- A wealth of with significant accomplishments both Translational Research and Medical Affairs activities in academia and/or industry
- Extensive experience in integrating diverse inputs from Clinical/Regulatory affairs, Scientific Affairs, Research & Development, and Sales/Marketing a plus
- Successfully directed and led Medical Affairs activities, disease awareness, and medical product training programs within a preeminent diagnostics company which resulted in the commercialization of clinical diagnostic test kits and instrument/reagent systems and adoption of tests in the setting of a results-reporting clinical diagnostics laboratory
- Strong technical background in the diagnostics industry - preferably immunodiagnostics and molecular diagnostics or related fields
- Must have authored and/or co-authored multiple articles and platform presentations that focus on clinical advances in the diagnostic industry and/or immunodiagnostics and molecular