



Example of Senior Manager, Regulatory Affairs Job Description

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Our company is looking to fill the role of senior manager, regulatory affairs. To join our growing team, please review the list of responsibilities and qualifications.

Responsibilities for senior manager, regulatory affairs

- Maintain a comprehensive understanding of relevant advertising/promotional regulations and guidances including those related to labeling, product promotion
- Participate according to business need on the marketing application development of new products' labeling as related to promotional labeling opportunities and restrictions
- Develop and implement strategies to facilitate the progress of Phase I through Phase III clinical development programs
- Review advertising, promotional and other related materials for assigned products to ensure compliance with applicable U.S. Food and Drug Administration (FDA) laws, regulations, and guidance
- Maintain a continued awareness and understanding of FDA regulations, guidance documents, and enforcement actions with regards to advertising and promotion of pharmaceutical products
- Serve as functional CMC representative on assigned New Product Development teams and related technical task forces In-Line projects such as site transfers
- Represents regulatory CMC and provides US regulatory filing strategy recommendations to interdisciplinary project teams
- Collaborate with commercial operation/marketing staff to mitigate regulatory risk on promotional labeling /communications
- Assess impact of and implement appropriate actions to new regulations, guidances, or enforcements

Qualifications for senior manager, regulatory affairs

- Proactively identify, develop, and execute initiatives, programs, partnerships, coalitions and stakeholder networks, with the objective of minimizing regulatory and scientific barriers and/or leverage regulatory and scientific opportunities to support our renew growth strategy
- Provide leadership, strategic and tactical direction execution and oversight of the Regulatory Advertising & Promotion review team, performing global LifeScan, Animas and Calibra Copy Review activities
- Partner with cross-functional reviewers
- Actively collaborate with senior marketing management to provide strategic direction to develop new campaign ideas
- Demonstrate a balanced approach to risk tolerance
- Provide management oversight, direction and support to team members