



# 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