Example of Director, Regulatory Affairs Job Description

Our company is looking for a director, 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 director, regulatory affairs

- Manages FDA liaisons and is responsible for regulatory strategy, tactics and direction to product development in preparation of submission documents, responses to queries by regulatory agencies
- Review, compile, and submit variations, new applications, supplements and amendments and periodic reports, responses to Health Authorities as needed
- Ensure that all regulatory submissions are of the highest regulatory standards
- Provide support to the Raheen site during Pre-Approval Inspections
- Determines global regulatory and registration requirements as required
- Supervises the assembly and compilation of necessary internal and external documentation for U.S. and global dossiers and product registration
- Represents Regulatory Affairs in Product Development Team Meetings and Product Advancement Team Meetings
- Determines regulatory strategy associated with the development of new drugs and biologics regulatory strategy for post-approval changes to drugs and biologics
- Maintains surveillance of regulatory intelligence and communicates this information to project teams
- Undertakes risk analysis and manages the outcome as appropriate

Qualifications for director, regulatory affairs

- Proactive stance and initiative
- Fluency with Word, Excel, and Powerpoint is recommended
- Minimum of 10 years pharmaceutical industry experience and 8 years regulatory experience
- Experience in preparation and management of successful IND/BLA submissions in US
- Experience liaising with FDA and leading teams to achieve successful Health Agency interactions