Example of Director, Regulatory Affairs Job Description

Our company is growing rapidly and is hiring 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

- Manage timelines in cooperation with project management, operations, subject matter experts and Regulatory Operations to ensure on time regulatory submissions
- Assist in review of IOPS change controls by cross-checking the description in regulatory filings in INDs/IMPDs, CTAs and BLAs/MAAs and to ensure that CMC related changes are reported to competent authorities in accordance with regulatory requirements
- Provide guidance on the processing of amendments to clinical trial CMC documentation
- Support establishing, managing and maintaining a knowledge base of current and emerging legislation and regulatory requirements and guidelines in the CMC field
- Assist in review of manufacturing change controls by cross-checking the description in regulatory filings in INDs/IMPDs, CTAs and BLAs/MAAs and to ensure that CMC related changes are reported to competent authorities in accordance with regulatory requirements
- Participate, as needed, in planning, organizing and managing the CMC component of pre-IND, pre-BLA and other Type C meetings with the FDA
- Assist with the planning, scientific writing and perform critical reviews of ex-US agency documentation, including but not limited to IMPDs, MAAs, amendments, variations and agency briefing documents that are related to

- Provide support to regulatory inspections, as needed, at the Raheen site or at other sites if the inspection relates to regulatory CMC issues
- Assist in tracking of CMC regulatory commitments for IMPDs, CTAs, and MAAs
- Participate, as needed, in planning, organizing and managing the CMC component of End-of-Phase 2 and pre-submission meetings with EMA and national competent authorities

Qualifications for director, regulatory affairs

- Senior leadership experience is required, including line management of multiple levels of reporting
- You have a degree from a top university
- You have a keen understanding of data, real-world evidence, and potential applications for clinical research and safety surveillance
- You are famailiar with oncology and the regulatory issues that are of particular interest in oncology (e.g., breakthough, EAP)
- You have a track record of success in developing long term relationships with regulatory agencies and life science partners in a strategic and abstract space
- You understand the common challenges faced by healthcare providers and life sciences firms and have experience bringing about mutually beneficial solutions