Example of Director, Regulatory Affairs Job Description

Our company is growing rapidly and is hiring for a director, regulatory affairs. To join our growing team, please review the list of responsibilities and qualifications.

Responsibilities for director, regulatory affairs

- Work with cross-functional teams to resolve emerging issues related to manufacturing operations with ex-US impact
- Manage timelines in cooperation with project management, SMEs and Regulatory Operations (Reg Ops) to ensure on-time regulatory submissions
- Assist in tracking of CMC regulatory commitments for INDs/IMPDs, CTAs, and BLAs/MAAs
- Support IOPS by providing CMC related guidances so that their short-term and long-term goals are achieved on time and with highest quality
- Manages activities to compile and organize data and documentation for NDAs, BLAs, MAAs, INDs, CTAs, associated supplements, amendments, variations, annual reports/notifications, expedited safety reports, and certificates of pharmaceutical product
- Attends and manages activities related to FDA-Sponsor meetings
- Evaluates and communicates impact of regulations related to products and processes
- Trains and coaches regulatory staff on SOPs, regulations and guidelines
- Reviews advertising/promotional materials for prescription drugs and biologics to ensure compliance with regulatory requirements
- Lead and drive all CMC submission activities (planning, authoring, reviewing, coordination, submission) for assigned projects/products

Qualifications for director, regulatory affairs

- Strong clinical foundation preferred
- Design well-informed global regulatory strategies
- Represent Regulatory Affairs on vadadustat project subteams and provide regulatory guidance (e.g., protocol reviews, report reviews, development plans)
- Assist in the preparation for regulatory agency meetings (e.g., Type C, Pre-NDA/MAA/NDS)
- Lead the coordination, preparation and timely submission of regulatory documents (e.g., INDs, MAAs, NDAs)