Example of Regulatory Strategy Job Description

Our company is searching for experienced candidates for the position of regulatory strategy. Thank you in advance for taking a look at the list of responsibilities and qualifications. We look forward to reviewing your resume.

Responsibilities for regulatory strategy

- Accountable for the interaction between the group and Affiliate Regulatory Affairs ensuring that local labelling complies with the Company Core Data Sheet (CCDS), deviations are identified and managed appropriately and all parties are informed and updated on a timely basis
- Manage & coordinate pre- and post-approval labelling translation, in compliance with EU/International guidance, including exchanges with EEA Health Authorities (and liaison with Middle East & African authorities when required)
- Review and monitor change control workflows for updates to labelling text and artwork for multiple products marketed across the globe
- Proactively identify potential issues and escalate to management for resolution
- May have responsibility for the development, maintenance and global implementation of core patient information leaflet
- Oversee maintenance of regulatory labelling and artwork repositories within the electronic document management system
- Accountable for the archiving of packaging artwork, including vial and container labels
- Responsible for leading, managing, developing and coaching the regulatory labelling and translation team
- Will be a member of the RA EMEA Franchise Leadership Team
- Oversee the development and management of suppliers/consultants for labelling and translation services ensuring projects are completed within

Qualifications for regulatory strategy

- Healthcare professional training & experience (RN, Pharm
- Bachelors or Masters or advanced degree in a scientific discipline, with a minimum of 6 years of increasingly responsible regulatory experience in the biopharmaceutical industry
- Ability to work with minimal supervision, to set priorities to meet timelines, to motivate others, and influence others
- Extensive knowledge of drug development, regulatory submissions and approval processes, including labelling requirements throughout the product lifecycle
- In-depth knowledge of health authority labelling regulations in Europe and ROW
- In-depth knowledge of labelling layout and design