Example of Regulatory Strategy Job Description

Our company is growing rapidly and is looking for a regulatory strategy. If you are looking for an exciting place to work, please take a look at the list of qualifications below.

Responsibilities for regulatory strategy

- Monitor and review financial information, updating where necessary in order to identify any anomalies or discrepancies and ensure management has access to up to date and accurate information to support the development of regulatory strategies and preparation of regulatory filings
- Develop pricing and tariff process and policy specifications and criteria and options and evaluate those options to support senior management decision-making in the application of regulation and pricing, such as in general rate cases, comprehensive rate plan filings and tariff administration proceedings
- Serve as a Global Labelling subject matter expert for all matters relating to the CCPIL
- Partner with Global Regulatory Leads and Company Core Datasheet (CCDS) teams to lead the evaluation, development and maintenance of CCPIL for assigned products
- Develop and maintain SOPs related to CCPIL
- Ensure local labelling complies with CCPIL where appropriate and ensure that all deviations are identified
- Review and assess impact of regulatory initiatives related to labelling IDMP, Braille, packaging and labelling systems readability and user consultation
- May lead industry association involvement on labelling topics, with EFPIA, DIA, LabelNet and other groups as necessary
- Assist in the design and implementation of best practices for the development of new labeling review and approval procedures and evaluation of existing procedures for practical application

and associated CCDS implementation plans

Qualifications for regulatory strategy

- This position must represent the interests of the Volkswagen Group on regulatory issues and serve as a "technical lobbyist/advocate" with regards to influencing and shaping future environmental requirements
- Solid scientific background, Ph.D., M.D., PharmD, MS, or BS with equivalent professional experience
- Ability to broadly represent department functions on project team in a matrix organization
- Experience in the pharmaceutical industry required with 5+ years direct regulatory affairs experience, including ex US regulatory experience
- Candidate should be comfortable working independently to create Health Authority correspondence (including request for Health Authority consultations), and attending specific project team meetings (such as Clinical Study Team Meetings) as the Regulatory Affairs Representative and providing guidance to project teams on all areas of pharmaceutical drug development (ICH, 21CFR)
- Serve as a primary contact with the FDA