



Example of Regulatory Lead Job Description

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Our company is hiring for a regulatory lead. 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 regulatory lead

- Ensure that all local product information used locally are up to date
- Collaborate with International RA Strategists to provide regulatory support to the Shire LOC and distributors in South Korea
- Collaborate with International RA Strategists to provide input into regulatory strategy/plans
- Prepare and submit investigational, marketing and variation applications, post-approval reports and other required life cycle management documentation for pipeline and inline products
- Monitor local regulatory requirements and communicate changes that have business impact to GRA and other relevant colleagues to enable the necessary measures can be taken by Shire to comply with new requirements
- Interact with regulators (and local distributors) where necessary to resolve questions or issues raised in the review of a regulatory submission
- Provide input into the internal change control tracking system to coordinate implementation of proposed post-marketing changes
- Initiate Artwork requests according to internal policies of Shire
- Notify GRA and relevant internal stakeholders of major regulatory milestone, submissions and notifications
- Review regulatory documentation prior to submission by the LOC, distributors/consultants to regulators authorities

Qualifications for regulatory lead

- Experience with multinational companies in international/ regional/ global regulatory affairs, with demonstrable experience in a regulatory leadership role
- Direct supervisory/ managerial experience
- Extensive regulatory experience within European RA
- Working experience within the MIDDLE EAST & AFRICA countries, relevant knowledge of other European or International regions is an advantage
- Regulatory or related experience in the pharmaceutical/ biotechnology industry