



Example of Regulatory Lead Job Description

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Our company is growing rapidly and is searching for experienced candidates for the position of 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 collaboration across RSU, including communication with regions and countries, to successfully deliver the agreed project scope in compliance with the RSU Management Plan
- Translate when necessary key regulatory communications from the local language to English for review and action by GRA and other internal colleagues
- Collaborate with Pharmacovigilance and Risk Management (PVRM) function in acting as the 'Safety Control Manager' for the LOC by assuming the role of the 'Nominated Contact Person for Pharmacovigilance' (NCPV) whereby the operational responsibilities will be supported by PVRM and outsourced as required
- Liaise with the Regional Pharmacovigilance Lead to ensure effective communication of safety information and oversight of the local quality management system in collaboration with Pharmacovigilance and Risk Management (PVRM)
- Review and verify regulatory information and submission plan captured within GRA databases when requested to do so
- Act as the main contact for designated portfolio and projects
- Act as the local RA lead in the CMLR process
- Participate in GRA and local LOC cross-functional team meetings
- Complete new and ongoing Shire training according to the prescribed due date

Qualifications for regulatory lead

- Monitor changes in the South Korean regulatory landscape
- A registered pharmacist in South Korea
- Pharmacovigilance experience in a pharmaceutical company
- Working experience within the TURKEY, relevant knowledge of other European or International regions is an advantage
- Representing the CDO on certain regulatory programs
- Ensuring that external commitments are appropriately structured, committed, planned, resourced and executed