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

## **Responsibilities for regulatory lead**

- Directly manage regulatory staff based in LOC dedicated to cover EEA region
- Lead EU staff meetings and participate in International/Global teams as requested
- Provide continuous assessment of resource requirements and plan resources in accordance, ensuring adequate internal and external staffing levels
- Provide input into the preparation and tracking into the International regulatory budget and ensure responsibilities for the regulatory LOC group expenses
- Develop strong and effective working relationships with local/regional commercial leads and their teams as part as Local R&D Team representation
- Provide strategic regulatory input to European Regional / Local R&D teams (across GRA, GMA, PVRM and other functions)
- Ensure regulatory LOC Leads provide relevant support to market access team (e
- Acting as a point of contact for the assigned projects and interfacing with key corporate functional areas review and completion of processes to ensure appropriate support to all regulatory staff based in LOCs
- Ensure compliance of regulatory activities in Regions that is consistent with Country laws and Shire internal protocols and procedures
- Makes recommendations for regulatory department operating procedures

## Qualifications for regulatory lead

markets

- Effective influencing, partnering and diplomatic skills
- Excellent and demonstrated written and oral communication skills
- Ability to advocate effectively in writing and in person
- BS, BSc, MS, MSc, PhD, PharmD, J.D., or M.D
- Generally has at least 8-15 years of Regulatory Affairs experience, including equivalent experience in the biopharmaceutical industry