



Example of Regulatory Lead Job Description

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Our growing company is hiring for a regulatory lead. To join our growing team, please review the list of responsibilities and qualifications.

Responsibilities for regulatory lead

- Assists the Regulatory Reporting and Issue Management Team by providing project support when needed
- Designs and implements regulatory strategies to obtain, maintain product investigative and marketing applications, and extend product registrations
- Be aware of commercial launch plans, provide regulatory guidance and strategic risk assessment to regional/local commercial teams and align strategies to ensure efficient collaboration and realistic plans to ensure timely regulatory actions
- In close collaboration with the EU Regulatory strategist Group Lead, ensure appropriate evaluation of local business and regulatory registration requirements for investigational and marketed products
- Will work with the EU A & P Head, EU regulatory strategist Head, Labeling team and Global Regulatory BU Leads and/or GRL to put in place appropriate processes and provide a common approach and partnership centrally, regionally, and locally
- Accountable for providing regional regulatory expertise, guidance/advice to internal groups on the European regulatory environment, including assessment of the impact of new and changing regulations/requirements in European member states on the development of strategic and tactical plans
- Active role in due diligence activities
- Gain clear understanding of European regulatory agencies organizational structure, roles and responsibilities, current regulations
- Ensure appropriate regulatory contact point for local regulatory authorities and external regulatory experts when necessary

Qualifications for regulatory lead

- Solid financial services industry background with experience in program management, reporting and/or controls
- Strong track record managing large-scale and complex programs of work
- Understanding of SPL and PIM formats, requirements and guidance for legacy and PLR labels and ability to communicate and resolve issues during labeling reviews and conversations
- Company-organized meetings of healthcare professionals
- Master's preferred or BA/BS with strong pharmaceutical industry experience (pre-clinical, clinical, medical, marketing, sales, manufacturing, operations, or government affairs)
- Experience in at least one regulatory affairs function outside of policy