



# Example of Manager Regulatory Affairs Job Description

Powered by [www.VelvetJobs.com](http://www.VelvetJobs.com)

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

## Responsibilities for manager regulatory affairs

- Review new Retail and Corporate products proposals from compliance perspective against local regulatory requirements
- Identify business impact for new regulatory requirements and escalate upwards as necessary
- Participate in the new product initiative process by reviewing new product proposals for compliance against local regulatory requirements and providing the Head of RAM with a report on these requirements
- People management, including hiring, coaching, training, development, performance review and management
- Represents Regulatory Affairs to company senior management
- Ensures implementation of standardization/new systems and processes to ensure efficiency and to support business continuity, including management of incoming and outgoing correspondence and archiving
- Obtains input from Marketing and Medical Affairs to formulate local label strategy ( , content, sequence of indications)
- Submits and obtains HA approval for initial and updated versions of local PI /Standard Export Package Insert (SEPI) as derived from CCDS
- Tracks submissions and approvals (version controlled)
- Develop and maintain strong relationships with staff in other departments, while monitoring and reporting on issues relevant to their work

## Qualifications for manager regulatory affairs

- Experience with electronic document management software
- Extensive Regulatory Affairs experience (5+ years) at both operational and strategic level (Head)
- Hands-on experience in pharmaceutical product registration (Head)
- Experience in Health Authority interactions
- Understanding of commercial business ( Head)