



Example of Regulatory Affairs Coordinator Job Description

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

Responsibilities for regulatory affairs coordinator

- Ensures compliance with local regulations and corporate policies and procedures as directed
- Support process improvements and implementation of best practices especially for archiving and other technical systems
- Assists in preparation of regulatory deliverables (report generation, presentations)
- Maintain and coordinate general regulatory documentation, including the Regulatory file room and archives
- Assist in the development and update of Standard Operating Procedures (SOPs) and/or Current Best Practices, as required
- Be responsible for the Certificate and Sample registration activities for diverse portfolio of global drug products working with other functions across sites and departments
- Be responsible for requesting certificates from Health Agencies, manufacturing sites and other affiliate offices and ensuring documents are correct and available in a timely manner
- Coordinate notarization & legalization of documents (in many cases working with government agencies)
- Organize and dispatch documentation to global affiliates against strict timelines as part of the approval process for global submissions
- Organize, request and track orders for registration samples, working with regional and local regulatory affiliates and Global Supply Chain personnel

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- Assist ASEAN RA maintain RA database and trackers
 - Extensive experience in working within a corporate team at a medium-large company
 - High degree of proficiency with Microsoft Excel as this is the tool used for daily data management
 - Ability to render clear and accurate judgements, make and document decisions and work independently
 - Knowledge and understanding of regulatory submission requirements, eCTD format, and other related material is essential
 - Must be fully cognizant of and responsive to shifting priorities and be able to interact with professional staff