



Example of Regulatory Affairs Coordinator Job Description

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

Responsibilities for regulatory affairs coordinator

- Provides information pertaining to product registration to SSUs, Design Owners, Solutions Management and other internal stakeholders as required
- Maintains updated tools for regulatory input into product development and maintenance, product licensing and related functions, based on information from members of the department
- Prepares basic documentation for medical device registrations as directed
- Submit regulatory medical device listing applications to international regulatory authorities as directed in accordance with agreed submission plans
- Raises purchase orders for non-stock purchasing within the department
- Act as point of contact to answer questions and support of activities related to operational/administrative tasks for preparation, submission and archiving of dossier
- Acquire knowledge of the local regulatory requirements in relation to projects assigned and gradually expand to general knowledge of regulations and guidelines applicable to product registration and manufacture
- Interacts closely with and provides guidance to local/regional/global RA and GDM function, manufacturing sites and other to obtain data required for projects assigned
- Develop, maintain and support cleaning of databases as directed for local/regional/global products
- Maintain and update regulatory files and records as required

- Knowledge of the medical device regulated environment
- Knowledge of applicable regulations and standards, 21 CFR 820, 801, 803, 806
- Must be able to manage several projects simultaneously
- Proficiency with Microsoft Office Products such as Word, Excel, Power Point, and SharePoint or equivalent software applications is preferred
- Must demonstrate effective research and analytical skills
- Assist ASEAN RA submission in 10 ASEAN countries