POSITION TITLE:
Senior Specialist, Regulatory Affairs

JOB PURPOSE

- Contribute to the planning and execution of registration strategies for medicinal products and medical devices in Singapore and Brunei to ensure timely and successful registration outcome.
- Maintain product registration details in MSD's databases in a compliant and timely manner
- Provide guidance to GHH and other functional groups to ensure local MSD's compliance with registration requirements as well as legal requirements administered by the Health Sciences Authority e.g. Health Products Act, the Medicines Act, the Poisons Act, Medicines (Advertisement and Sale) Act etc.

MAIN RESPONSBILITIES

PLANNING: Strategize, streamline and enhance regulatory processes and ensure timely regulatory filing and approval of new products, product line extensions, product labeling updates and quality-related changes. This is to ensure alignment of product availability with business plans and compliance with internal standards.

STAKEHOLDER ENGAGEMENT: Guide colleagues on Singapore and Brunei registration and regulatory requirements, liaise with headquarter groups on submission strategies, review and analyse the scientific contents of registration dossiers to ensure compliance with current regulatory expectations and work closely with the regulatory authority to ensure successful & timely regulatory outcomes.

IMPLEMENTATION: Ensure flawless execution of agreed filing plans and facilitate the launch of the new/changed product.

PROFILE:	**Qualification:** • A graduate degree in Biological/Chemical Sciences/Pharmacy. Singapore-registered pharmacist is preferred but not essential. **Experience:** • At least 5 years of relevant commercial pharmaceutical regulatory affairs experience and knowledge and the ability to work cross-functionally and independently to drive results. A good team player with excellent communication skills and good working attitude.

For job applications, you may submit your resume via email to sim.min.tee@merck.com. Please take note that only shortlisted candidates will be notified.

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