BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Senior Manager - Regulatory Affairs at Procter & Gamble, Indonesia

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Will play an essential role in building clear strategic business direction, building a robust regulatory affairs organization and work closely in collaboration with Lifecycle management



Apply now !

You will be responsible for and lead all regulatory activities in Indonesia. In this role, you will play an essential role in building clear strategic business direction, building a robust regulatory affairs organization and work closely in collaboration with Lifecycle management and Innovation regulatory affairs team!

YOUR TEAM
This role reports to Director of Regulatory Affairs ASEAN and can look forward to being a part of the bigger ASEAN team. The team manages P&G health products of brands Vicks, Neurobion, Sangobion, Seven Seas, Iliadin, etc.

What Success Looks Like
Lead and enable team to effectively deliver Business objectives, base business, franchise innovations, strategies. Demonstrated partnership with Technical & Commercial Leadership to ensure robust business deliverables including regulatory considerations. Smooth day to day operations & timely high-quality delivery on programs across Indonesia. Robust regulatory monitoring, anticipating changes and timely implementation to meet requirements. Build a strong well integrated GPS Team.

Responsibilities Of The Role

- Leading a team of Regulatory professionals to deliver a compliant Indonesia Consumer health business
- Collaborate with Indonesia leadership team on broad business & organization matters
- Leading local registration strategy and planning for base business & new product development to support business objectives
- To ensure a qualified registration dossier is prepared and meeting with the most current requirements in timely manner
- Lead internal & external approval process of new pack materials, POSM and advertisement materials
- Ensure all relevant regulatory systems and databases are maintained up to date
- Actively participate in cross functional meetings or coordination meetings for projects regionally and globally
- To stay updated with the upcoming changes in regulatory legislation and guidelines and define impact to business
- Negotiate and take a lead in driving regulatory bodies on registrations of new products, variations and renewals. Take any necessary actions in order to accelerate the approval
- Build and maintain close relationship with registration authorities and other relevant pharmaceuticals organizations/bodies.

QUALIFICATIONS

- Graduate with degree (Bachelors/Masters) in Pharmacy. Registered pharmacist with Ministry of Health is preferred
- Having more than 8 years experience in product registration (consumer products, supplements, medicinal products) and dealing with related government agencies, i.e.: BPOM, Kemenkes
- Knowledgeable with related regulations of product registration (consumer products, supplements, medicinal products) and corresponding activities (BPOM, Kemenkes)
- Knowledge and experience in GMP, GDP regulations will be an advantage
- Experience with managing team
- Communication Skills - Able to clearly present information to non-technical leadership teams through the spoken word. Able to write and speak clearly and effectively in English to the team
- Decision Making & Problem Solving - Able to take action in solving problems while exhibiting judgement and a realistic understanding of issues, able to use reason, even when dealing with emotional topics
- Policy and Procedures - Able to relate to routine operations in a manner that is consistent with established policies and procedures
- Analytical Skills - Able to use a systematic approach in solving problems through analysis of problem and evaluation of alternate solutions
- Proficient in English- both written and oral
- Proficient in Computer systems

Apply now !