(Sr.) Regulatory Affairs Specialist

Job ID
REQ-10026354
Oct 20, 2024
Taiwan

Summary

-Contributes and support the development of submission of product registration, progress reports, supplements, amendments, and/or periodic experience reports. Supports all registration activities of the Department to ensure compliance with the requisites of the local pharmaceutical regulatory environment.

About the Role

Major accountabilities:

- Achieve the best product registration with commercially attractive labelling in accordance with registration plan -Maintain and secure product license in terms of CMC/CDS/safety update according to local regulations/law/guidelines, company strategy and global compliance -Ensure compliance with code of conduct, relevant regulations and laws for related CPO activities (DRAGON update, RMP, packing materials, promotional materials/activities, PMS/drug safety reporting etc.) -Foster and maintain good relations with internal and external stakeholders -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable).

Key performance indicators:

- Project & stakeholder feedback -Product license update in terms of CMC in agreed timeline -Adherence to Novartis policy and guidelines

Minimum Requirements:
Work Experience:

- Drug regulatory affair
- Functional Breadth.
- Cross Cultural Experience.
- Operations Management and Execution.
- Project Management.

Skills:

- Pharmacisit preferred
- Analytical Skill.
- Collaboration.
- Detail Oriented.
- Lifesciences.

- Project Planning.
- Regulatory Compliance.

Languages :

- English.

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Division
Development
Business Unit
Innovative Medicines
Location
Taiwan
Site
Taipei
Company / Legal Entity
TW03 (FCRS = TW003) Novartis (Taiwan) Co. Ltd
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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