Sr. Regulatory Affairs Specialist

Job ID
REQ-10000668

四月 24, 2024

Taiwan

Summary

-Contributes and support the development of submission of imported 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:

- Support product license registration / License maintenance for existing products, i.e. CMC variations, IPL updates, license renewals, etc.
- Follow local HA regulations to update product-related changes in a timely manner
- PMF registration and GMP follow-up renewals
- PSUR & RMP submission

- Regulatory and documentation support for other function/ TAs e.g. Market Access, KAM, Marketing, promotion materials review
- Abide by internal SOPs and update RA systems in a timely manner
- Other assignments

Key performance indicators:

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

Minimum Requirements:
Work Experience:

- at least 1-2 year experience in Drug regulatory affairs

Education:

- Bachelor's degree or above, major in pharmacy or medical science-related fields

Languages :

- Excellent command of written and spoken English and Mandarin Chinese.

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Division
Development

Business Unit
Pharmaceuticals

國家
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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