Regulatory Affairs Specialist

Job ID
REQ-10056545
Jul 01, 2025
South Korea

Summary

Location: Seoul, Korea #LI-Hybrid

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

This is a 2 years contract position.

We are looking for a RA Specialist that contributes and support the development of submission of product registration, progress reports, supplements, amendments, and/or periodic experience reports.

We are looking for a RA Specialist that gives and support the development of submission of product registration, progress reports, supplements, amendments, and/or periodic experience reports. They would also support all registration activities of the Department to ensure compliance with the requisites of the local pharmaceutical regulatory environment.

About the Role

Key Responsibilities:

- To set registration plan, to perform product registration in accordance with registration and launch plan, & maintain product license with local regulation and global compliance strategy
- Review new projects and aset development plan (timeline etc.) in collaboration with Global DRA and related CPO functions (Marketing, HE&P and CD&MA etc.)
- 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
- Perform IND application & get approval to ensure study timeline in collaboration with medical team and Global DRA
- Ensure compliance with NP4, KRPIA code of conduct, relevant regulations, and laws for related CPO activities (DRAGON update, RMP, packing materials, promotional materials/activities, PMS/drug safety reporting etc.)
- Develop and maintain good relations with internal and external partners.

Essential Requirements:

- Preferably 2-3 years of experience in the pharmaceutical industry in a relevant field such as regulatory affairs, registration, or a directly related area
- Korea pharmacist license is preferred
- Languages: Good command in English (speaking and writing)
- Good Interpersonal skills
- Strong Project Management
- Ability to work under pressure

Commitment to Diversity and Inclusion / EEO paragraph

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Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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Division
Development
Business Unit
Innovative Medicines
Location
South Korea
Site
Seoul
Company / Legal Entity
KR01 (FCRS = KR001) Novartis Korea Limited
Functional Area
Research & Development
Job Type
Full time
Employment Type
Temporary (Fixed Term)
Shift Work
No
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