Regulatory Affairs Specialist

Job ID
REQ-10066806

11月 30, 2025

South Korea

摘要

Location: Seoul, Korea #LI-Hybrid
This is a contract position of 1 year (1 Jan -31 Dec 2026).

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

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 Regulatory Affairs 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

Novartis are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

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

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Development

地点
South Korea

站点
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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