Regulatory Affairs Specialist/Sr.Regulatory Affairs Specialist

Job ID
REQ-10036522

1月 21, 2025

South Korea

摘要

-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

Key Responsibilities:

- 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 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.)
- 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)

Essential Requirements:

- **For Specialist level -** Preferably 1-2 years of experience in the pharmaceutical industry in a relevant field such as regulatory affairs, registration, or a directly related area.
- **For Senior Specialist -** Preferably 3-4 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.

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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部门
Development

Business Unit
Innovative Medicines

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
Regular

Shift Work
No

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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.

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