Regulatory Affairs Specialist/Sr.Regulatory Affairs Specialist

Job ID
REQ-10041021
Mar 06, 2025
Corea del Sur

Resumen

-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

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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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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

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Ubicación
Corea del Sur
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Functional Area
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Full time
Employment Type
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Shift Work
No
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