NOVARTIS

Regulatory Affairs Specialist

Job ID
REQ-10015305
Juli 28, 2024
Südkorea

Summary

Internal Role Title: Regulatory Affairs Specialist

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.

About the Role:

The RA specialist sets registration plan and perform product registration in accordance with registration, launch plan, and maintain product license with local regulation and global compliance strategy.

About the Role

Key Responsibilities:

- Review pipeline and set the registration strategy in collaboration with global RA and related CPO functions with support from senior specialist and manager.
- Achieve the best product registration with efficient label by conducting research on submission requirements and approval lead time in accordance with registration plan.
- Support launches (artwork, barcode, Drug ID mark, etc.)
- Perform CTA and get approval to ensure study timeline in collaboration with other CPO functions. Support IMP management through confirmation of variant number.
- Maintain product license by handling variations for label, quality (CMC and mfg. site) and administrative changes according to local law/regulation/guidelines, company strategy and global compliance.
- Secure product license by handling re-evaluation, renewal, re-examination or HA safety communication. Ensure post approval activities (website, artwork, etc.)
- Submit RMP by supporting of other function in line with global direction. Be accountable for accurate and timely update of RA compliance registration database
- Ensure industry compliance with NP4, KRPIA code of conduct. Support cross functional activities by delivering regulatory input.
- Understand basic knowledge on the legal frameworks, internal processes, GxP’s. Keep abreast of relevant laws /regulations and apply to related CPO activities. Ensure reporting and follow up of all spontaneous adverse events (AE) and technical complaints for all Novartis products according to respective SOP
- Foster and maintain good relations with internal and external partners. Communicate optimally with HA

and other BFs and understand RA internal working process and handle own task well.

Essential Requirements:

- Preferably 1-2 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

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