

Regulatory Affairs Specialist

Job ID
REQ-10028536
Nov 04, 2024
South Korea

Summary

Internal Role Title: Regulatory Affairs Specialist

Location: Seoul, Korea #LI-Hybrid

This is a contract position of 1 year (1 Jan -31 Dec 2025).

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 is to support the dossier preparation, submission and approval from MFDS for NTO related product registration and maintenance complying with Regulations and SOPs.

About the Role

Key Responsibilities:

- Support to prepare dossiers for NTO related new products registration & approved products maintenance and support to obtain NTO related approvals from MFDS.
- Support the NTO related CTA actions in collaboration with relevant Stake Holders (e.g., medical team, global team, CTA Hub etc.), if required.
- Ensure NTO related Novartis compliance with P3, KRPIA code of conduct, relevant regulations and laws for related CPO activities (DRAGON update, RMP, artwork, barcode, Drug ID mark, promotional materials/activities, PMS/drug safety reporting etc.).
- Ensure reporting and follow up of all spontaneous adverse events (AE) and technical complaints for all Novartis products according to respective SOP
- Any other NTO related RA activities, if needed

Essential Requirements:

- 3-4 years university degree preferably majored in chemistry, biology or pharmacy.
- 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
- 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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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>

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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cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

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