NOVARTIS

Regulatory Affairs Specialist

Job ID
REQ-10086969
сен 03, 2026
Южная Корея

Сводка

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

About the Role

Major accountabilities:

- **Major accountabilities**
- 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 optimal 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 managing 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 managing Reevaluation/Renewal/Reexamination /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 correct and timely update of RA compliance (registration) database (DRAGON)
- 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 stakeholders.
- Communicate effectively with HA and other BFs
- Understand RA internal working process and handle own task well

- **Essential Requirements**
- Education: 4-year university degree, preferably in Pharmacy, Biochemistry, Chemistry, Life Sciences, or a related field
- Languages: Fluent in both written and spoken English
- Experience: Pharmaceutical industry experience preferred
- Knowledge: Basic understanding of regulatory affairs, drug development process, and applicable pharmaceutical regulations/guidelines preferred

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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Дивизион
Development
Business Unit
Development
Место
Южная Корея
Сайт
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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