NOVARTIS

Regulatory Affairs Specialist

Job ID
REQ-10086961
сен 03, 2026
Южная Корея

Сводка

-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

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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