

# Regulatory Affairs Specialist

Job ID REQ-10066806

11月 30, 2025

South Korea

# 摘要

Location: Seoul, Korea #LI-Hybrid

This is a contract position of 1 year (1 Jan -31 Dec 2026).

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

We are looking for a RA Specialist that contributes and support the development of submission of product registration, progress reports, supplements, amendments, and/or periodic experience reports.

We are looking for a Regulatory Affairs Specialist that gives and support the development of submission of product registration, progress reports, supplements, amendments, and/or periodic experience reports. They would also support all registration activities of the Department to ensure compliance with the requisites of the local pharmaceutical regulatory environment.

### About the Role

## Key Responsibilities:

- To set registration plan, to perform product registration in accordance with registration and launch plan, & maintain product license with local regulation and global compliance strategy
- Review new projects and aset development plan (timeline etc.) in collaboration with Global DRA and related CPO functions (Marketing, HE&P and CD&MA etc.)
- 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
- Perform IND application & get approval to ensure study timeline in collaboration with medical team and Global DRA
- 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.)
- Develop and maintain good relations with internal and external partners.

# **Essential Requirements:**

- Preferably 2-3 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

### Commitment to Diversity and Inclusion / EEO paragraph

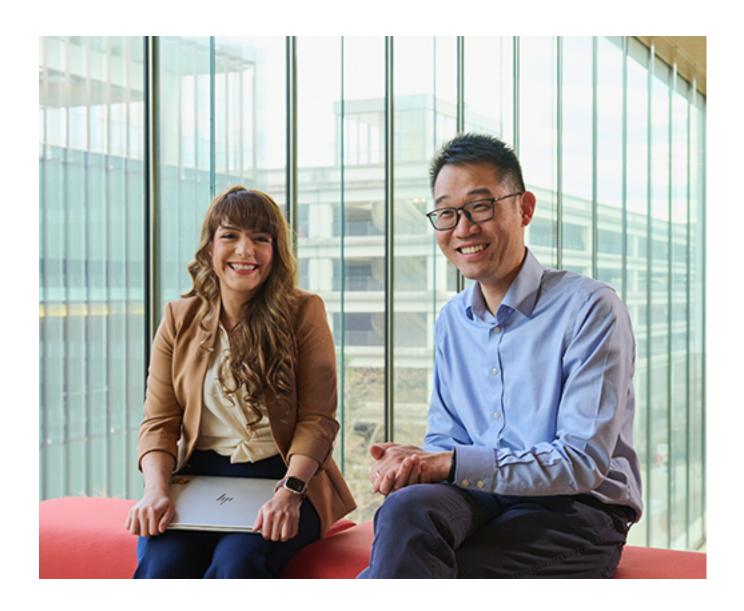
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Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter

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部门 Development	
Business Unit Development	
地点 South Korea	
站点 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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