

# Regulatory Affairs Manager

Job ID  
REQ-10011271  
Juli 28, 2024  
Vietnam

## Zusammenfassung

Internal Role Title: Regulatory Affairs Manager Location: Hanoi, Vietnam #LI-Hybrid This role is based in Hanoi, Vietnam. Novartis is unable to offer relocation support for this role. Please only apply if this location is accessible for you. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you. As Regulatory Affairs Manager, you will ensure of regulatory compliance and achieving registration approval on time from local authority, in line with company's objectives.

## About the Role

### Key Responsibilities:

- Ensure of assigned product portfolio registration submission and approval on time (new registration including new site, renewal registration, variations), in line with local commercial strategies.
- Ensure regulatory compliance for a balanced life-cycle management: safety label change, labeling, CMC, RMPs, PSUR and other MA lifecycle support are performed in accordance with local regulations and relevant Novartis SOPs
- Coordinate with QA/Supply chain departments to support for product's availability on market.
- Develop and maintain effective working relationships with Drug Administration of Vietnam and key Partners to support current and future business activities (which are under responsibility of Regulatory Affairs).
- Proactively involve on shaping regulation as assignment by time.
- Ensure compliance to current local regulations: Awareness of current and new local regulations. Interpretation and communication of any changes that may impact Novartis in a timely manner to all relevant Partners as per assignment to ensure timely implementation of new regulations and reflect on business strategy.
- Ensure adherence to Global and local processes & Process improvements: Compliance with Global processes and proactively identify areas of improvement with regards to local compliance.
- Ensure maintenance of DRA Regulatory database: correct and timely DRA Regulatory database in Global systems and Local record; Perform other tasks relating to Regulatory activities as assigned.

### Essential Requirements:

- University degree or equivalent experience in Pharmacy

- Minimum 5 years' experience in Drug Regulatory Affairs in MNC or Drug Administration of Vietnam.
- Critical thinking with attention to detail; Analytical and problem-solving skills; Written and oral communication skills; Influencing & negotiation skills
- Language: English & Vietnamese

### 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>

### Commitment to Diversity & Inclusion:

We are committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

**Join our Novartis Network:** If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>

**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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Business Unit

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Ort

Vietnam

Website

Vietnam

Company / Legal Entity

VN04 (FCRS = VN004) NVS Vietnam Company Ltd

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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