Regulatory Affairs Manager

Job ID
REQ-10058853

7月 30, 2025

Vietnam

摘要

Location: Hanoi #LI-Hybrid

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

About the Role:

As a Regulatory Affairs Manager in Vietnam, you are the strategic bridge between innovation and patient access. You will lead the charge in securing and maintaining marketing authorizations for a diverse portfolio of life-changing medicines, ensuring compliance with both global standards and Vietnam ' s evolving regulatory landscape.

This role is supporting and ensuring that registration milestones of global and regional projects/brands are met, and functional excellence including compliance is achieved. Supports RA CO Head in developing registration strategies including business continuity by obtaining and maintaining all marketing authorizations of products under responsibility. Contributes to converting new regulatory policy into tangible regulatory strategies, including interfacing with external

stakeholders.

This position to be based in Hanoi.

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

Commitment to Diversity and Inclusion / EEO paragraph:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams

representative of the patients and communities we serve.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

部门
Development

Business Unit
Innovative Medicines

地点
Vietnam

站点
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

Apply to Job

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

Job ID
REQ-10058853

Regulatory Affairs Manager

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10058853-regulatory-affairs-manager

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Vietnam/Regulatory-Affairs-ManagerREQ-10058853-2
5. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Vietnam/Regulatory-Affairs-ManagerREQ-10058853-2