Regulatory Affairs Manager

Job ID
REQ-10011271
Jul 22, 2024
Vietnam

Summary

Internal Role Title: Regulatory Affairs Manager Location: Hanoi, Vietnam #LI-Hybrid 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. This position to be based in Hanoi.

About the Role

Your Responsibilities:

Your responsibilities include, but not limited to:

- 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.

What you'll bring to the role:

- 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.

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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 future together? https://www.novartis.com/about/strategy/people-and-culture

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Division
Development
Business Unit
Innovative Medicines
Location
Vietnam
Site
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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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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Job ID

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