NOVARTIS

Regulatory Affairs Manager

Job ID
REQ-10077683
Aug 06, 2026
LOC_VN

About the Role

Key Responsibilities

- Ensure of assigned registration submission and approval on time (new registration, renewal registration, variations including new site), in line with local commercial strategies.
- Ensure regulatory compliance for a sustainable life-cycle management: safety label change, labeling, CMC, 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.
- Collaborate with commercial team for launching preparation, tender management and promotional material management.
- Ensure of regulatory database updated (DRAGON, REDI, RA Shared documents ...)
- Develop and maintain effective working relationships with Drug Administration of Vietnam and key Stakeholders 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 Stakeholders 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.
- Perform other tasks relating to Regulatory activities as assigned.

Minimum Requirements

- University graduate, preferably with a degree in Pharmacy or Medicine
- Fluent in English and Vietnamese, enabling effective local and global collaboration
- 5+ years of experience in Drug Regulatory Affairs or Drug Registration Management
- Strong critical and strategic thinking, with proven communication, influencing, and negotiation capabilities
- Demonstrated independent and innovative mindset, solid understanding of product-relevant bioscience, and ability to build trust-based relationships with key regulatory authorities

Role Requirements

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Division
DIV_GD
Business Unit
Development
Location

LOC_VN
Site
Vietnam
Company / Legal Entity
VN04 (FCRS = VN004) Novartis Vietnam Company Ltd
Functional Area
FCT_RD
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Regulatory Affairs Manager

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