NOVARTIS

Regulatory Affairs Head, Vietnam

Job ID
REQ-10068854
Jun 11, 2026
LOC_VN

About the Role

Key Responsibilities

Strategic & External Leadership

• Build and maintain strong relationships internally across Therapeutic Areas and functions, and externally with DAV, MoH, and key stakeholders to influence and manage regulatory and legislative changes.

• Develop and execute best-in-class Regulatory Affairs strategies to achieve accelerated approval timelines and optimal labeling outcomes. Monitor, anticipate, and communicate regulatory changes, ensuring alignment with local, Regional, and Global RA teams.

• Represent Novartis in regulatory interactions and ensure outcomes are clearly documented, communicated, and escalated.

Regulatory Accountability, Lifecycle maintenance, compliance & Supply Continuity

• Be accountable for all regulatory and legislative aspects of the product portfolio in compliance with Vietnam regulations and Novartis policies. Lead lifecycle maintenance activities including site transfers, variations, renewals, labeling changes, and post-approval commitments, etc,,, to ensure uninterrupted supply.

• Ensure proactive regulatory planning to minimize risk and prevent supply disruption. Oversee all RA workload to ensure high-quality, compliant files, timely submissions and approvals.

Cross-Functional & Business Partnership

• Collaborate cross-functionally with Commercial, Medical, Quality, Supply Chain, Legal, and Regional/Global teams to ensure alignment on priorities and objectives.

• Act as the central RA contact point between local, Regional, and Global stakeholders. Ensure regulatory strategies support launch readiness, supply resilience, country growth plan and portfolio value.

People Leadership & Organizational Excellence

• Lead the Regulatory Affairs function, providing clear direction and governance. Recruit, coach, and develop a high-performing, engaged regulatory team.

• Drive efficient team performance, optimal resource utilization, and sustainable delivery. Continuously enhance regulatory operational excellence and capability.

Essential Requirements

- University degree in Pharmacy, Medicine, or a related scientific discipline.
- Minimum 10 years of Regulatory Affairs experience within the pharmaceutical industry in Vietnam.
- Strong knowledge of Vietnam’s healthcare environment, regulatory processes, and authority expectations.
- Proven experience developing regulatory strategies to support product launches and lifecycle management.
- Strong stakeholder management capabilities with the ability to influence in a highly matrixed organization.
- Demonstrated leadership experience in building, coaching, and developing teams.

- Ability to anticipate regulatory risks and plan proactively to ensure supply continuity.
- Fluent proficiency in Vietnamese and English, both written and spoken.

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.

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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