

Senior Regulatory Affairs Manager

Job ID
REQ-10011271
Nov 12, 2024
Vietnam

About the Role

Key Responsibilities:

- Regulatory Strategy/Financial - Supports RA CO Head in developing registration strategies including business continuity by obtaining and maintaining all marketing authorizations of products under responsibility. Contributes to convert new regulatory policy into tangible regulatory strategies. Comprehensive knowledge within Regulatory. Provide comprehensive advice on a wide range of issues that are different, but related.
- Regulatory Strategy/Financial - Provides regulatory advice to internal and external stakeholders and make independent decisions. Provides comprehensive advice on a wide range of regulatory issues. Provides authoritative regulatory advice and recommendations to influence internal and external stakeholders. Subject matter expert for complex regulatory activities. Understands the needs of the organization and aspects of the external environment. Makes decisions independently within action plan.
- Regulatory Strategy/Financial - Develops and manages specific initiatives to deliver tactical results. Effectively manage team to submit regulatory applications for business franchise/division in Vietnam within the agreed timeframe. Communicate regulatory issues that have high visibility/business impact to RA Head in a concise, accurate and timely manner. Responsible for keeping within assigned budget.
- Managerial- Development of subordinates through appropriate delegation and training. This role has managerial responsibility for others, in second line, with key accountability for success of complex CO project and submissions. Accountable for the recruitment, training, development and retention of associates.
- Managerial-Direct resource utilization and ensure synergy in order to maximize efficiency and ensure appropriate prioritization so that deliverables & timelines are met. Provide associates with opportunities for growth and development, ensure quality development plans, develop and retain key talent and ensure succession planning. Serve as role model and embrace Novartis Values and Behaviors.
- Operational Excellence-Conduct thorough risk assessment and mitigation plan to ensure high quality Submissions. Provide regular updates on projects and activities to RA Head.

Essential Requirements:

- Science based BS or MS with requisite experience and demonstrated capability. Advanced degree (MD, Ph D, PharmD) preferred.
- Excellent English required
- Extensive knowledge and experience of Vietnam regulations, guidelines and regulatory processes
- At least 10 years of relevant experience in drug development within the pharmaceutical industry, including membership of international development project teams and cross-functional global initiative teams.

- Strong leadership skills and at least 5 years' experience in leading positions
- Proven records of extensive CO knowledge/experience in NDA and the life cycle management of products within the pharmaceutical industry; entrepreneurial mindset.
- Proven records in leading cross-functional, and cross-cultural teams (project and/or direct reports).
- Excellent interpersonal, communication and negotiation skills, and proven ability to work effectively in a cross-functional and international matrix environment.

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>

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>

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>

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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