Senior Regulatory Affairs Manager

Job ID
REQ-10011271
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République socialiste du Viêt Nam

Résumé

Internal Role Title: Senior Regulatory Affairs Manager

Location: Hanoi, Vietnam #LI-Hybrid

This role is based in Hanoi, Vietnam. Novartis is unable to offer relocation support for this role. Please only apply if this location is accessible for you.

Senior Regulatory Affairs Manager 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 convert new regulatory policy into tangible regulatory strategies, including interfacing with of external stakeholders.

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

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

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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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