RA Sub-Region Head Asia Pacific

Job ID
REQ-10020574
Sep 05, 2024
Singapore

Summary

Internal Role Title: RA Sub-Region Head Asia Pacific

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Location: Singapore #LI-Hybrid

About the Role:

Regulatory Affairs Sub-Region Head Asia Pacific is to ensure development development and registration milestones of global and regional projects/brands are met, and functional excellence including compliance is achieved.

Drives development of registration strategies including lifecycle management for the region in close collaboration with RA Country Heads, Regional New Product Strategy, Global RA organization and commercial stakeholders in sub-region. Drives translation of regulatory policy into tangible regulatory strategies, including management of external stakeholders. In collaboration with RA Region Head, drive collaborative, enterprise thinking and cross-functional collaboration at sub-region and country level.

About the Role

Key Responsibilities:-

- **Product Registration and Key Life-Cycle Management -** Sets up development and registration objectives with country RA teams in alignment with RA Region Head and Commercial teams' objectives in geographic area of responsibility. Accountable for setting optimal regulatory strategy and driving the execution of the strategy in the geographic area of responsibility during product development and registration phase.
- **Product Registration and Key Life-Cycle Management -** Ensures optimal use of regulatory strategic opportunities by country RA teams to ensure acceleration of priority products during filing and registration. Participates in Launch Readiness Reviews and provides strategic regulatory input for key markets in the geographic area of responsibility, as required. Partners with Regional New Product Strategy, GPRDs, GTALs and RA Country Heads ensuring effective resolution of regulatory strategic differences/issues between GPTs and regional commercial management.
- **Functional Excellence -** Drives regional functional expertise and is accountable for the implementation of RA functional excellence activities in the assigned countries in line with global RA guidance or strategy. Accountable for the implementation of compliance activities and associated processes by country RA

teams.

- **Functional Excellence -** Provide strategic guidance and support to RA Country Heads. Ensures in alignment with RA Region Head appropriate level of RA resources in countries of assigned geographic area. Sets up and implements optimal systems/collaborations for the exchange of best practice(s) across the country RA teams, working in close partnership with the other RA Sub-Region heads.
- **External Focus -** Translates regulatory intelligence in the assigned countries into tangible regulatory strategy for Novartis Portfolio in cooperation with the country RA teams and global or regional RA policy roles. Shapes regulatory environment by active participation at relevant HA meetings including influencing and negotiations in alignment with country RA teams and Global Development Strategy.
- **External Focus -** Represents Novartis on the appropriate international trade association(s) and relevant external forums to leverage and shape regional regulatory guidelines and standards for the Novartis Portfolio. Ensures budget targets are met and provides input into RA budgets in the geographical area of responsibility
- **People -** Partnering with appropriate stakeholders drives effective hiring, development and training of RA Country heads and associates in line with Global/regional RA vision. Drives the RA OTR discussions for the cluster. Responsible for the development of RA country Heads. Coaches and mentors RA country Heads as appropriate.

Essential Requirements:-

- Master in Life Sciences degree. PhD or Higher Degree or equivalent experience desirable
- Minimum 7 -10 years' experience in drug development and registration at global or country level.
- Experience with countries in Asia Pacific will be an advantage. Excellent inter-personal skills
- Proven strong leadership skills. Experience leading leaders will be an advantage. Ability to develop and communicate strategic vision
- In depth understanding of the regulations and pharmaceutical business models in assigned region, awareness of regulations in other major regions (e.g. EU, US). Shows cultural awareness
- Ability to work in a cross-functional environment. Highly committed and team oriented.
- Excellent communication and negotiation skills. Proven track record of HA negotiations
- Ability to travel and represent the organization

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

Division
Development
Business Unit
Innovative Medicines
Location
Singapore
Site
Mapletree Business City (MBC)
Company / Legal Entity
SG90 (FCRS = SG015) Novartis Asia Pacific Pharmaceuticals Pte. Ltd
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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