RA Head India

Job ID
REQ-10025796
Oct 25, 2024
India

About the Role

Major activities
• Design strategic vision for the RA India and ensures its successful execution
• Manages RA CO India budget in line with set targets
• Product Registration and key life cycle management activities
- Sets up product development and registration objectives in aligment with RA Sub-Region Head, RA MOW Head New Product Planning, Regional Commercial team objectives and in close partnership with the local LT (Leadership team).
- Accountable for setting optimal regulatory strategy and driving the execution of the strategy in India of responsibility during product development and registration phase.
- Ensures optimal use of regulatory strategic opportunities to ensure acceleration of priority products during filing and registration, including innovative filings approach such as local trial waiver, without CPP, in parallel to reference countries fillings, local testing waiver, product advocacy activities, etc
- Directs the team for optimal and quality presentation of regulatory documentation to be presented to the Health Authorities such as DCGI and State FDA.
- Participates in Launch Readiness Reviews and provides strategic regulatory input for India business as required.
- Partnering with RA Sub-Region Head, and RA MOW Head of New Product Planning to ensure development and registration milestones of global, CO and regional projects/brands are met.
• Functional Excellence
- Drives functional expertise and is accountable for the implementation of RA functional excellence activities in India in line with regional and global RA guidance/strategy.
- Accountable for the implementation of compliance activities and associated processes for the entire Novartis portfolio. Provide strategic guidance and drive/support.
- Ensures in alignment with RA Sub-Head Region appropriate level of RA resources in India.
- Sets up and implements optimal systems/collaborations for the exchange of best practice(s) across including with other Novartis divisions / offices as appropriate, working in close partnership with the other RA GDD Country Heads
• External focus
- Ensuring successful Health Authority meetings at all levels- SEC meeting, Technical meeting, Individual project negotiation meeting
- Establishes and maintains strong relationships with key Health Authority decision makers, directs cross-Franchise regional advocacy efforts in partnership with internal Novartis advocacy / policy groups.
-Takes India leadership role to develop and support contacts with industry associations such as OPPI, ISCR, IFPMA and other forums to ensure Novartis priorities are supported.
- Translates regulatory intelligence in India into tangible regulatory strategy for Novartis portfolio in

collaboration with regiona/global RA policy roles.
- Shapes regulatory environment by active participation at relevant HA meetings including influencing and negotiations in alignment RA GDD Sub-Regional Head and Global Development Strategy and local Govt Affairs colleagues.
- Drives portfolio advocacy with key authorities such as Ministry of Health, ICMR, DCGI, DoP etc in parnership with RA GDD Sub-Region Head, RA MOW Head New Product Planning and Regional/global policy team and local Govt affairs team.
- Represents Novartis on important Industry associations such as OPPI/ ISCR/ IFPMA/ FICCI and relevant external forums to leverage and influence regulatory guidelines and standards for the entire Novartis portfolio.
• People
- Assesses, in alignment with RA Sub-Region Head, appropriate level of RA resources in India.
- Drives effective hiring, functional development and training of associates in line with Regional and Global RA vision and Country Leadership policies.
- Responsible for assessment of associates during the P&O process (e.g. EVOLVE check-in and Team Retro meetings as operational manager, participation in Country Leadership and regional RA OTR reviews) in close collaboration with the RA P&O Business Partner.
Key Performance Indicators
• Recognized by internal stakeholders as competent and reliable partner in driving India regulatory strategy and represents RA at country Leadership Team.
• Number of achieved standard and stretch registration milestones/deliverables.
• Time to market of new launches with competitive labeling.
• Completeness/accuracy of India Requirements list at all times and timely communication of regulatory environment changes in assigned countries to respective global stakeholders.
• Successful people development (within the RA GDD organization and beyond).
• Proof of implementation and sustainability of RA functional excellence across Novartis portfolio of assigned countries.
• Proof of implementation and impact of regulatory and commercial intelligence within India.
• Achievement of Regulatory compliance deliverables as per global targets within India.
• Timely, accurate and proactive regulatory related communication of general or project-specific items to local/ regional key stakeholders as appropriate.

Education (minimum/desirable): Master in Life Sciences degree. PhD or Higher Degree or equivalent experience desirable
Languages: Fluent in English (mandatory)
Experience / Professional Requirement: • Minimum 15 years experience in drug development and registration
• Proven track record of successful HA negotiations
• Ability to work in a cross-functional, cross- country environment and across Novartis products. .

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
Sandoz
Location
India
Site
Mumbai (Head Office)
Company / Legal Entity
IN01 (FCRS = IN001) Novartis India Limited
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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RA Head India

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