

Director - Medical Affairs

Job ID
REQ-10064364

10月 16, 2025

India

摘要

The Global Medical Affairs team acts as enterprise medical voice across the asset lifecycle and leads the medical strategy for the therapeutic area.

Develops/ owns IEP and provides input into development while ensuring US and Int'l medical perspective is reflected.

Is responsible for the implementation of medical strategies for early programs globally with focus on innovative evidence solutions including interventional studies, NIS and RWE studies and implementation science projects.

Based on extensive experience in drug development will be able to lead Integrated Evidence Packages in situations with higher scientific complexity and potential regulatory challenges. Will manage the most complex assets and those that potentially will require deeper pharmacovigilance expertise.

Will act as a subject matter expert in the development of the overarching strategies, providing inputs during design and along the end-to-end execution of programs across different disease areas.

Will provide leadership and deep medical expertise in the TA, pivoting support based on business priorities and will represent GMA with senior stakeholders when needed

Acts a strategic partner to NIBR, Development, International Medical Affairs, US MA

Acts as Global Medical Affairs responsible for review of Managed Access Programs (MAPs) Acts as

Global Medical Affairs responsible for Post Study Drug Supply (PSDS)
Represent Global Medical Affairs at GPTs and be a strategic partner to life-cycle management of In-Market brands
Responsible for medical information related activities to the Therapeutic Area

About the Role

Director Medical AI & Innovation

Location - Hyderabad #LI Hybrid

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Key Responsibilities:

- Lead development and execution of medical affairs strategy for TA/Asset priority programs including transformative tactics such as: research/population health, innovative partnerships and integrated evidence plans
- Co-develop plans for evidence generation, MSL / Field Medical Affairs strategy, medical education programs, scientific publication planning and Medical Expert network development with TAs
- Represent GMA around prioritized portfolio with internal and external audiences, in collaboration with TAs including the investment, medical and regulatory communities, as well as pharmaceutical or biotechnology industry collaborators/partners
- To review a new MAP request within two working days, following receipt of all required information.
- Create MAP treatment strategy worldwide plan for compounds and seek leadership endorsement, in co-ordination with line functions including program safety
- Development of patient consent / assent, product form, baseline / follow-up questions, Statistical Analysis Publication Plan (MSAPP) & other relevant activities, as applicable
- Develop PSDS cover letter to highlight any new or additional compound-specific information for the physician (e.g. relevant risk minimization materials)
- Review the PSDS Treatment Plan and the PSDS-specific patient consent requirements on an ongoing basis (at a minimum annually) for any relevant updates and liaise with global safety regulatory and other relevant line functions, as needed

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.

Essential Requirements:

- MD (Preferred) or PhD/PharmD in Health Sciences. Specialist Degree or specialist qualification related to discipline for which you will be responsible is an advantage.
- At least 10 years in Pharmaceutical Industry experience in Medical Affairs and/or Clinical Development
- Critical thinker and with ability to navigate uncertainty with major supervision.
- Fluent oral and written English; Other relevant languages are an advantage.
- Able to establish credibility and influence across a range of diverse stakeholders in a matrix organization to drive change.
- Ability to truly collaborate across functions and markets: serve-partner-co-create.
- Able to navigate in an environment of shared outcomes and cross-business accountabilities.
- Firm working knowledge of GCP, scientific and clinical methodology, protocol designs, management and regulatory requirements for clinical studies designated for review by regulatory authorities.

Desirable Requirements:

- Highly preferred: TA expertise, significant medical affairs early asset lifecycle, pre-launch and launch experience.
- Experience in developing and executing “Best in Class” processes at scale.
- Clinical trial research experience conducted in a pharmaceutical or equivalent academic environment in TA of interest is strongly desired.

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Commitment to Diversity and Inclusion:

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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>

部门
Development

Business Unit
Universal Hierarchy Node

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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