NOVARTIS

Medical Governance Lead

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Сводка

The Medical Governance Manager is the accountable owner for medical governance, SOPs, compliance, MLR oversight, audit readiness, and MAP governance. The role ensures consistent, high quality and compliant execution of Medical Affairs activities in line with Novartis good practices, local regulations, and global medical governance standards. Operating within the Medical Governance, Evidence & Operations pillar, the role enables robust medical governance frameworks, supports audit readiness, and drives continuous improvement of Medical Affairs processes across therapeutic areas. The role acts as a key connector between Medical Affairs teams, Legal, ERC, Pharmacovigilance (PV), and other assurance functions to safeguard scientific integrity. The Medical Governance Manager does not hold final approval authority unless explicitly defined, and operates under the accountability of the Head, Medical Governance, Evidence & Operations.

About the Role

Key Responsibilities:

Medical Governance Frameworks & Standards

- Ensure the highest quality standards and compliance of Novartis good practice guidelines and country regulations.
- Implement and maintain country-level medical governance frameworks aligned with Novartis good practices and global standards.
- Support adherence to local regulations and internal policies across Medical Affairs activities.
- Coordinate governance-related processes across therapeutic areas to ensure consistency and transparency.
- Own and coordinate governance training assignment tracking and completion reporting; maintain evidence for inspection readiness.
- Run periodic monitoring/self-inspections of Medical Affairs activities and document outcomes and follow-ups.
- Enable end-to-end visibility of medical governance activities for the Head, Medical Governance, Evidence & Operations.
- **undefined**

Compliance, Audit Readiness & Risk Management

- **Support Medical Affairs audit preparedness, inspections, and follow-up actions in collaboration with Quality, Legal, ERC and PV**
- **Track, document and monitor audit findings, observations and remediation plans.**
- **Identify governance risks and process gaps and escalate appropriately.**
- **Support and coordinate medical governance review forums/committees (as applicable) to ensure timely, compliant review and documentation of scientific/medical materials.**
- **Contribute to continuous improvement initiatives following audits or internal reviews.**
- **undefined**

SOPs, Processes & Ways of Working

- **Coordinate periodic review and update of Medical Affairs SOPs (Standard Operating Procedures) and governance documentation.**
- **Support implementation of updated processes and guidance through clear communication and training inputs.**
- **Monitor adherence to defined governance processes and flag deviations.**
- **Ensure governance guidance and process support for transparency/disclosure obligations and conflict-of-interest risk mitigation (in alignment with relevant policies).**

Cross-functional Governance Interfaces

- **Act as a key interface between Medical Affairs and Legal, ERC, PV, Regulatory Affairs and other assurance functions.**
- **Support governance alignment for medical activities such as Medical Information, MAPs (Managed Access Programmes) and evidence generation activities, without duplicating ownership.**
- **Support governance aspects of vendor/third-party qualification and oversight for Medical Affairs activities (as applicable).**
- **Enable timely and compliant execution of Medical Affairs initiatives through early governance engagement.**

Governance Reporting & Insights

- **Contribute to governance-related metrics, dashboards and reporting as defined by the Medical Governance, Evidence & Operations pillar.**
- **Support preparation of governance updates for internal reviews and leadership forums.**
- **Ensure governance documentation and records meet data integrity expectations (complete, traceable, inspection-ready).**
- **Use insights from audits, metrics and operational feedback to inform continuous improvement actions.**
- **undefined**

Essential Requirements:

· % compliance of Medical Affairs activities with governance standards and SOPs

- Number and trend of governance deviations
- Audit and inspection readiness status at any point in time
- % of audit findings closed within agreed timelines
- Number of overdue CAPAs
- Recurrence rate of similar audit findings
- % of SOPs reviewed and updated as planned
- Adoption rate of harmonized Medical Affairs ways of working
- % on-time completion of mandatory governance and compliance training
- Trend in governance issues linked to capability or training gaps
- Timeliness of governance support to medical initiatives
- Use of governance metrics and insights to drive improvement actions

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Other
Место
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Functional Area
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Job Type
Full time
Employment Type
Regular
Shift Work
No

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