

Manager Medical Governance & Operations

Job ID
REQ-10033373
Dec 09, 2024
Kenya

Summary

Guided by the Medical Governance & Operations Team (GOT) in Global Health Medical Affairs (GHMA), fills this role for sub-Saharan Africa (SSA). Defines the key priorities and risks involved in implementing Novartis standards, policies, guidelines and processes in SSA as they relate to clinical & medical operations, scientific engagement & communication, and medical information services; as well as leads the Medical and Clinical monitoring & oversight requirements to enable compliant execution of activities across SSA.

About the Role

Major accountabilities:

- Lead the End-to-End medical governance of regulated (GxP) activities (IS, NIS, IIT, MAP, RC, RWE), in alignment with Medical tactical plans and priorities
- Advise and guide the activity/business owner to implement processes related to due diligence, governance and oversight of Third Parties engaged in Evidence and Data Generation Activities, and the reporting and dissemination of the data – including Scientific Engagement & Communications and Medical Information Services (SEC & MI)
- Manage the SSA Local Medical Affairs Governance Committee (LMAC)
- Is the local SSA expert on, and monitors, adherence to Novartis processes and standards; referring to local country regulations when needed
- Support data quality/integrity in SSA medical affairs
- Provide Governance support, advice, coaching and expert input to activity owners and relevant teams
- Maintain overview and monitor progress of issues, ensure & track escalation and follow-up until resolution
- Monitor and report KPI/KQI using existing Global systems & tools
- Proactively identify risk and support risk management and mitigation
- Ensure proper classification of local medical activities
- Oversee and monitor audit & inspection readiness and execution at SSA level, in close collaboration with regional/local QA, as well as with GHMA GOT
- Track deviation and support implementation/resolution of CAPA raised during audit/inspection at HQ level
- Proactively identify root cause and implement action to improve future audit/inspection performance
- Understand the systems that enables key processes in order to give advice and guidance to activity owners
- Be the single point of contact for partner functions such as Development, QA, Ethics-Risk-Compliance (ERC), Patient Safety, Global Medical Affairs (GMA), Procurement and others
- Proactively participate in global/regional cross-divisional medical governance networks for ensuring continuous improvement
- Share common objectives across these networks for ensuring a consistent and harmonized governance

and training across medical affairs

- Track execution of training for the SSA Medical Team, working closely with the GHMA GOT

Key performance indicators:

- GMA standards are implemented locally and activities are executed in a compliant way; potential risks are identified and mitigated
- Compliance risks for assigned responsibilities are identified with well-defined processes and appropriate internal level of controls
- Internal Audits without critical findings for assigned functions and accountabilities
- Preventive action plans in place and implemented in an effective and timely manner
- Oversight through established KPIs/KQIs on existing systems E. g., GxP Training Compliance

Impact on the organization:

- Role has a direct impact on the reputation of Novartis at global and regional/local level
- Direct impact on the local business practices

Decision making:

- Need to align with GHMA GOT, Ethics-Risk-Compliance and other GxP line functions locally

P&L / associates:

- Individual contributor

Background & Experience:

- Excellent English (oral and written) skills
- Scientific Degree, PhD, PharmD or equivalent.
- Extensive and relevant experience in pharmaceutical industry (at least 5 years).
- Knowledge and understanding of:
 - Both scientific and operational aspects of clinical drug development
 - GCP, ICH, and relevant regulations
 - GMA standards and Novartis standard operating procedures
- Skills:
 - Leadership and proven planning and management skill
 - Strong communication and ability to communicate complex information in simple terms
 - Process excellence
 - Change management mindset to sustain a culture of high ethical standards and compliance
 - Negotiation and problem-solving skills for bridging between scientific and business
- Proactive and team-player approach for managing effective international and matrix collaboration

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

Corporate Affairs

Business Unit

Innovative Medicines

Location

Kenya

Site

Kenya

Company / Legal Entity

KE03 (FCRS = KE003) NVS Kenya Limited

Alternative Location 1

Ghana, Ghana

Alternative Location 2

Ikeja, Lagos, Nigeria

Alternative Location 3

Ivory Coast, Ivory Coast

Alternative Location 4

Midrand, South Africa

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

[Apply to Job](#)

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

Job ID

REQ-10033373

Manager Medical Governance & Operations

[Apply to Job](#)

Source URL: <https://prod1.id.novartis.com/careers/career-search/job/details/req-10033373-manager-medical->

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. <https://www.novartis.com/careers/benefits-rewards>
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Kenya/Manager-Medical-Governance---Operations_REQ-10033373-1
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Kenya/Manager-Medical-Governance---Operations_REQ-10033373-1