Group Lead Medical Safety operations

Job ID
REQ-10055604

6月 30, 2025

India

摘要

-The Group Lead, Medical Safety Operations (MSO), is responsible for managing a group of Medical Safety Experts (MSE) and Senior Medical Safety Experts (Sr MSE) within MSO. This is accomplished by organizing and planning of the deliverables of the Team.

He/she may keep an oversight of all outsourced activity for Medical Safety function. Acts as point of contact for global Medical Safety for the External Service Providers (ESPs) performing outsourced activities. Leads and supports projects that are within the scope of medical safety operations.

The Group Lead is also responsible for the development and implementation of:
- Enhanced medical safety quality processes and procedures.
- Enhanced line function excellence and standards.

About the Role

Major accountabilities:

- Manage a group of MSE & Sr MSE within the MSA&EE. Ensure that their deliverables are met according to the agreed standards and timelines.
- Ensure and drive compliance & quality of deliverables to consistently high standards.
- Participate in the MSA&EE management strategy and operational plan.
- Ensures optimal communication and feedback between the Therapeutic Areas and the Medical Safety Experts.
- Support the Head of Med Safety Assessment & ESP Engagement in soliciting and forecasting future requirements for the MSA&EE.
- Participate in organizing and planning the work of the MSE & Sr MSE as per Therapeutic area aggregate reports and other documents schedule and ad-hoc urgent activities i.e. Health Authority Requests.
- Liaise with the Head Patients Safety and Global Program Safety Leads to get feedback on the performance of the MSE & Sr MSE and ensure that adequate training is put in place accordingly.
- Is responsible for overall training and career development planning for the team MSO.
- Develops effective relationships with internal and external stakeholders to ensure successful outcomes of objectives.
- Participate in analyzing the workload of the Team based on a detailed Work-Unit assessment.
- Liaise, support, and represent the MSA&EE during Audits and Inspections undertaken at PS&PV.
- Cross functionally collaborates with other work teams of PS&PV and represent MSA&EE in common forums.
- Contribute to the MSA&EE resource planning.
- Build a high performing group of MSE & Sr MSE and recruit, retain and develop best talent; assess resource needs on a regular basis to achieve ongoing process improvements, to provide sufficient process excellence support and to create/maintain a sustainable compliance culture.
- Keeps an oversight of all applicable outsourced activities related to medical function.
- Acts as point of contact for global Medical Safety for questions related to outsourced activity.
- Supports quality and compliance lead to ensure quality and compliance of all outsourced activities.
- Ensure transparent and clear communications with ESPs.
- Participate in applicable ESP governance meetings.
- Collaborate with the ESPs and provide trainings as necessary.
- Support onboarding and training activities within Medical Safety.
- Ensures completion of all MRQC arbitrations in timely manner from ESPs. Ensure timely completion of scores for OSCM related to medical function.
- Work in close collaboration with Head of Med Safety Assessment & ESP Engagement for early identification of issues related to ESPs.
- Represents Medical Safety in cross-functional and/or cross-departmental initiatives which aim to improve processes and ensure a quality and compliance focused environment either by direct involvement or by ensuring appropriate Line Function representation.
- Collaborates with PS&PV QA and Global Development Clinical Quality and supports the implementation of the Pharmacovigilance Quality Plan.
- Tracks, reports and follows-up to completion all Corrective Actions and Preventative Actions (CAPA) identified during audits and inspections.
- Identifies, manages and reports on Medical Safety Key Quality Indicators. Recommends corrective actions and ensures all relevant follow-up activities are completed based upon

report outputs.
- Ensures compliance to and supports adequate training opportunities for new SOPs and Business Guidance. In collaboration with LF and QA, ensures individuals comply with Novartis PV processes.
- Tracks deviations from SOPs in Novartis QMS and in collaboration with QPPV office and PV compliance department, ensures appropriate documentation is filed and corrective actions are taken.
- Provides backup support for the Head of Med Safety Assessment & ESP Engagement.

Key Performance Indicators (indicate how performance for this role will be measured)

Efficiency of MSA&EE Team management and support underlined by delivery of high-quality activities/tasks to the therapeutic areas. Quality of the liaison between the MSA&EE and the Therapeutic Areas for work planning organization. Timeliness, quality, and efficiency of the results obtained through targeted training for the Team, Efficient strategy of the activity/task planning for the MSA&EE under responsibility in the Therapeutic Areas. Recruitment, retention and development of talents in the MSA&EE. Finalization of all scores related to medical function (ICSR and PSUR) well within timelines. Health Authority Inspections and internal audits have no critical findings related to the Medical Safety function accountabilities in particular for quality and regulatory compliance due to medical function. Successful implementation of improvements as measured by sustainable changes and improved efficiency. Creative & innovative thinking for operational excellence, best practices and lessons learned.

Job Dimensions (Indicate key facts and figures)

Number of associates:

Up to 15 associates (direct reports)

Financial responsibility:

(Budget, Cost, Sales, etc.)

Participation to the medical Safety operations resource planning.

Impact on the organization:

Scheduling and management of the Medical Safety Operations work in the different MSO circles.

Cooperation between the Medical Safety operations and the medical function for work planning organization and efficiency of deliverables.

Ideal Background:

Education: Advanced degree or equivalent education/degree in life science/healthcare. MD, MBBS, PharmD, PhD preferred.

Language: Fluent in spoken and written English.

Experience:

Required professional experience:

- 8 years in drug development in a major pharmaceutical company (of which 3 are in a global position in safety/clinical/medical affairs or other relevant line function at an operational or medical position)
- Demonstrated people management experience (direct/matrix).
- Strong leadership and people management skills, with ability to successfully lead, engage and develop a highly effective team.
- Excellent negotiation, conflict resolution, decision making, problem solving, communication (written and verbal) and presentation skills
- Results driven, self-starter with proactive working style, committed and accountable, transparent working style also under pressure.
- Quality oriented.
- Good planning, organizational and computer skills.

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Innovative Medicines

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Hyderabad (Office)

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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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