

# Medical Safety Processes & Projects Lead

Job ID

392516BR

Jul 12, 2024

India

## Summary

This role combines responsibilities in Medical Safety Operations (addressing pharmacovigilance (PV) needs) with broad Project Management activities. Reporting to the Head Medical Safety (MS) Processes & Projects, the MS Processes and Projects (MS P&P) Lead is responsible for an appropriate prioritization and planning of deliverables associated with MS owned processes and other key initiatives impacting MS. The MS P&P Lead will provide leadership & operational planning/execution support of all process development/improvement activities (or other initiatives, incl. applicable business case development to succession) related to Medical Safety provisioned, led and/or supported by MSO. The MS P&P Lead is accountable to ensure adequate quality and compliance in relation to process executions (with or without involvement of IT systems) in Medical Safety through driving initiatives as well as inspection readiness via process (and where applicable, IT systems) maintenance and/or improvements. The MS P&P Lead supports planning and coordination of daily operational activities to ensure process responsibilities of MSO are consistently met with high quality and according to timelines.

## About the Role

### Major accountabilities:

- Exhibit leadership and accountability for Medical Safety (MS) owned/supported processes (and IT systems) by way of regular reviews to identify gaps / issues and/or improvement needs (e.g., optimizations, retirements, automations, etc.) which can be addressed through projects (incl. applicable business case development to succession and correct prioritization); projects should result in improved performance (incl. quality) and/or compliance (considering internal and external/regulatory requirements).
- Exhibit leadership and accountability for initiatives provisioned, led or supported by Medical Safety Operations (MSO) to safeguard deliverables, quality as well as timelines incl. necessary support and course corrections and contingency planning as applicable (e.g., deputy identification and knowledge transition).
- Lead compliance in assigned activities and challenge 'as-is' for continuous improvement and assure inspection readiness.
- Lead proactive identification of risks / issues via close monitoring (incl. conductance of effectiveness checks and monitoring of metrics).
- Provide subject matter expertise, guidance & support for process creation and/or updates incl. management of Medical Safety related process issues (both internal and external). This may include providing direct support or arrangement of support from MSO (i.e., through deputy or coordinate with Head P&P for SME identification) as concerns new or ongoing initiatives impacting on processes within Medical Safety and PS&PV (as applicable).
- Support Head MS P&P in strategic and tactical communications related to process changes and other

key initiatives as applicable.

- Act as thought partner/coach supporting MS P&P Managers to operationalize their objectives including strengthening their skills, capabilities and overall professional growth.
- Support Head of MS P&P and other MSO Group Leads in creating transparency and sharing key learnings and best practices for continuous improvement (i.e., design, development and delivery of strategy and processes).
- Provide support and/or deputize for Head MS P&P as needed (e.g., in process review board meetings).
- Support readiness preparations for PV Audits/Inspections and provide support during PV Audits/Inspections incl. act as SME where applicable.
- Exhibit accountability for successful integration of M&A to BAU state by providing necessary SME support incl. procuring expert input where necessary.
- Exhibit leadership behavior to foster compliance and to build/nurture strong relationships with internal key stakeholders/customers/partners through exhibiting Novartis values (inspired, curious, unbossed & self-aware) in Medical Safety.
- Ensure completion of applicable trainings in a timely manner.

### **Minimum Requirement**

- Advanced degree or equivalent education in Healthcare / Life Sciences. MD, MBBS, MSc, Pharm D, PhD preferred.

At least 10 years (of at least 5 years in a global role) of project management (at least 5 years as a project leader) and/or Process ownership experience in a pharmaceutical or healthcare consulting setting, preferably in drug safety (i.e., Pharmacovigilance), clinical research, or regulatory affairs (incl. appropriate business case development)

- Solid knowledge in drug safety related processes (incl. authoring procedural documents, workflow design)
- Proven ability to work with large cross-functional teams in complex initiatives
- Results-driven, self-starter with proactive working style, committed and accountable, transparent working style also under pressure
- Quality oriented
- Proven ability for clear and concise communication tailored to a diverse audience and effective cross functional collaboration, stakeholder engagement and teamwork
- Very good planning, organizational and computer skills
- Sense of urgency and ability to manage multiple priorities under a changing environment
- Excellent negotiation, conflict resolution, decision making, problem solving, and presentation skills

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Division

Development

Business Unit

Innovative Medicines

Location

India

Site

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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