

Head Medical Safety Process & Projects

Job ID
REQ-10068214

12月 09, 2025

India

摘要

Providing leadership, oversight and expertise with respect to Processes, Procedures (including involvement of appropriate systems) and Projects relevant for Medical Safety. Responsible for driving and/or facilitating process developments / improvements (incl. simplifications) considering external as well as internal needs. Strategically leading and driving compliance standards as well as audit inspection

readiness via process improvements in Medical Safety. Representing Medical Safety (if applicable) in cross-functional and/or cross-departmental initiatives aiming at improvement of processes and systems

About the Role

Major accountabilities:

- Oversee process improvements (incl. standardization, simplification), retirements as well as

the development of new processes and procedures (based on business needs, addressing compliance gaps/ liabilities) across therapeutic areas in Medical Safety

- Ensure adherence of Medical Safety processes to regulatory requirements, global safety regulations, and conformity with PS & PV procedures and processes.
- Responsible for having oversight on the Projects within Medical safety involving other PS&PV subfunctions or other GDD line functions
- Ensure seamless transition of complex and comprehensive process changes to Projects and support their successful execution.
- Responsible for setting and generating quality metrics for medical review of safety cases, management of safety signal in the SPOT system, CSR/TPSR review timelines in collaboration with other sub functions as appropriate
- Ensures effective implementation of processes and conventions by Medical Safety colleagues throughout PS & PV.
- Ensure business needs / objectives are adequately addressed by processes and procedures, and thereby, quality and compliance targets in Medical Safety are met.
- Provide expertise, guidance & support for process updates and management of process related issues; this may include direct support or arrangement of support for the preparation & review of updates of procedural documents. Support may also include the creation of new processes and procedures
- Develop synergies, address issues, and ensure the fulfillment of all Medical Safety responsibilities with respect to processes owned by functions other than Medical Safety
- Identify and assign the right team members / SMEs for new processes and coordinate the SME participation (from Medical Safety) as concerns new or ongoing initiatives impacting on processes with Medical Safety involvement
- If needed/ applicable, interact with Health Authorities globally to address any issues related to Medical Safety processes, support readiness preparations for PV Audits/Inspections and provide support during PV Audits/Inspections
- Participate at Process Review Board Meetings (if needed) to resolve potential issues related to Medical Safety processes
- Represent Medical Safety in cross-functional and/or cross-departmental initiatives aiming at improvement of processes
- If needed / applicable, act as Process Owner and/or Project Owner (Business Lead) in Medical Safety and/or Subject Matter Expert representing Medical Safety as concerns process(es) / project(s) owned by other functions
- If needed / applicable, deputize for the Global Head of Medical Safety Operations with respect to process change affairs / issues
- Coach process owners and SMEs in Medical Safety on strategy, scientific as well as process simplification aspects as needed (e.g., organizing training, workshops)
- Build & lead a high-performance team and recruit, retain and develop best talents; assess resource needs on a continued basis to meet process excellence objectives and maintain a sustainable compliance culture.
- As member of the MSO Leadership Team proactively support defining and executing (if applicable) MSO strategy in alignment with PS&PV strategic priorities.

Key Performance Indicators -

- Establish and successfully maintain ' Process Excellence ' as institution / platform providing expertise & support, sharing experiences and best practices [Feedback from stakeholders].

- Driving or facilitating process improvements (e.g., standardization, simplification), new processes and/or process retirements [Number of process changes / impact of process changes, e.g., regarding quality of deliverables, process efficiency, compliance].
- Effective & efficient collaboration with other PS&PV functions including PVSO [Feedback from stakeholders].
- No critical findings at Audits / Inspections with respect to Medical Safety processes.
- Adequate implementation / closure on time of Corrective and Preventative Action (CAPA) plans related to Medical Safety processes.

Job Dimensions (Indicate key facts and figures)

- Number of associates: Up to 10 direct & indirect reports
- Financial responsibility: (Budget, Cost, Sales, etc.) NA
- Impact on the organization: Medical Safety processes and thereby, fostering compliance and ensuring deliverables of high quality. Accountable for process developments (changes) in Medical Safety. Drives change management mindset of compliance throughout Medical Safety. Exhibits strategic leadership behavior to foster compliance.

Ideal Background (State the required education and experience level)

- Education: Advanced degree or equivalent education / degree in Life Sciences / Healthcare. MD, MBBS, PharmD, PhD preferred.
- Languages: Fluent in spoken and written English

Experience: Required professional experience:

- At least 8 years in drug development in a major pharmaceutical company (of which 5 are in a global position in drug safety / clinical / medical affairs or other relevant line function at an operational or medical position)
- 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 and presentation skills
- Proven ability for clear and concise communication tailored to a diverse audience and effective cross functional collaboration, stakeholder engagement and teamwork
- Solid knowledge in drug safety related processes
- Results driven, self-starter with proactive working style, committed and accountable, transparent working style also under pressure
- Quality oriented

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部门

Development

Business Unit

Development

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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