Medical Safety and Processes Manager

Job ID
REQ-10017856

11月 15, 2024

Spain

摘要

-Monitors and audits the company ' s drug, biologics or medical devices surveillance program including the intake, evaluation, processing and follow-up on adverse reports. Participates in the resolution of any legal liability and in complying with government regulations. Ensures accurate receipt, maintenance and assessment against product labeling. Reports events or reactions as required by regulatory agencies including adverse events data from clinical trials, spontaneous or solicited sources, periodic and experience reports. May provide trending and safety signal detection and assessment. Supports all clinical trial activity and post marketing.

About the Role

This position can be based in Barcelona, Spain. The **Medical Safety and Processes Manager** will provide operational planning / execution support to assigned process development/improvement activities related to Medical Safety provisioned, led and / or supported by Medical Safety Officer.

The role combines responsibilities in Medical Safety Operations (addressing pharmacovigilance (PV needs) with Project Management activities. Reporting to the Head Medical Safety (MS) Processes & Projects, the MS Processes and Projects (MS P&P) Manager is responsible for planning of deliverables associated with MS owned processes and other key initiatives impacting MS.

The successful candidate 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 their assigned initiatives as well as inspection readiness via process (and where applicable, IT systems) maintenance and/or improvements.

Your key responsibilities, but not limited to:

- Lead and coordinate Medical Safety owned processes (and IT systems) with support of Process and Projects Lead in conducting regular reviews to identify improvement needs which can be addressed through projects and support development of the appropriate business case
- Exhibit leadership and accountability for assigned initiatives provisioned, led or supported by Medical Safety Operations to safeguard deliverables, quality as well as timelines incl. necessary support
- Support or lead compliance in assigned activities and challenge ‘as-is’ for continuous improvement and assure inspection readiness
- Support or lead proactive identification of risks / issues via close monitoring of assigned processes
- Provide subject matter expertise, guidance & support for process creation and / or updates incl. management of Medical Safety related process issues (both internal and external).
- Support Head MS P&P in communications related to process changes and other key initiatives as applicable.
- Support team in creating transparency and sharing key learnings and best practices for continuous processes, projects and / or departmental improvement
- Provide support and / or deputize for MS P&P Lead as needed
- Support readiness preparations for PV Audits / Inspections and provide support during PV Audits/Inspections incl. act as SME where applicable.
- Foster strong relationships with key internal stakeholders and customers through demonstrating company values (inspired, curios, unbossed and self-aware) in Medical Safety.

What you’ll bring to the role:

- At least 6 years (of at least 3 years in a global role) of project management (at least 2 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
- Solid knowledge in drug safety related processes (incl. authoring procedural documents, workflow design)
- Proven ability to work with cross-functional teams in initiatives
- Results-driven, self-starter with proactive working style, committed and accountable, transparent working style also under pressure
- Proven ability for clear and concise communication tailored to a diverse audience and

effective cross functional collaboration, stakeholder engagement and teamwork
- Sense of urgency and ability to manage multiple priorities under a changing environment
- Good negotiation, conflict resolution, decision making, problem solving, and presentation skills

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

Languages: Fluent in spoken and written English

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We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity, and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world ' s toughest medical challenges. Because the greatest risk in life, is the risk of never trying! Imagine what you could achieve here at Novartis!

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

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to diversity.inclusionch@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Why Novartis: Helping people with disease and their families takes more than innovative science. It

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部门
Development

Business Unit
Innovative Medicines

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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