

Governance Manager, Patient Orientated Program (Part-time 0.6 FTE)

Job ID
REQ-10037978
Feb 19, 2025
Irlanda

Resumen

-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.

Drive the end-to-end POP (primarily Patient Support and Market Research Programs) process and governance in the respective country organization, or assigned cluster of countries

Ensure the local implementation of the Novartis POP standards, policies, guidelines and processes

Assess local risks for Novartis related to POPs and establish risk mitigation plans

About the Role

Major accountabilities:

- Responsible for the full implementation of the Local POP Governance Framework which enables the end-to-end POP process, embeds Medical, Quality, Patient Safety, Regulatory, Ethical, Risk and Compliance requirements and facilitates cross functional stakeholder involvement. at the same time, ensuring alignment with local laws and regulations
- Provide guidance and support for local associates involved in POPs throughout the program lifecycle; Develop and deliver training for local associates and management to ensure standards are well understood and followed by all associates.
- Manage and oversee all Governance and POP monitoring activities at country organization or assigned cluster of countries.
- Lead the Local POP Governance Board or equivalent body ensuring timely and comprehensive review of programs and POP related issues.
- Proactively identify quality and compliance risks, establish mechanisms to mitigate these risks in collaboration with risk experts and Implement controls to measure compliance; review audit outcomes and perform country self-assessments as needed. Escalate issues if necessary to the GGO and local senior management.
- Participate in cross-functional initiatives, global task forces and project teams. Act as an integral member of local implementation team, working closely with key stakeholders to drive POP strategy and implementation in the local organisation (e.g, One PSP, Project Enhance etc)
- Support preparation for of health authority inspections, internal audits related to POPs, as needed
- Be an ambassador for the Novartis values and behaviours and support the journey towards an inspired, curious, unbossed and self-aware organization
- Establish and maintain effective communication channels with global and local teams and senior leaders

at Novartis, to continuously enhance the Novartis POP standards and share best practices.

- Support the/Chief Medical Office in the development and implementation of the Novartis POP standards, policies, guidelines, and procedures.
- Other tasks as required.

Key performance indicators:

- Adherence to Novartis policy and guidelines -Project & stakeholder feedback -Operational risk mitigation and audit/inspection findings -Quality and timely reporting of KPI and safety reports/updates -Results of audits/inspections

Minimum Requirements:

Work Experience:

- Functional Breadth.
- Managing Crises.
- People Challenges.
- Project Management.
- Operations Management and Execution.
- Collaborating across boundaries.

Skills:

- Databases.
- Employee Training.
- Pharmacovigilance.
- Project Management.
- Reporting.
- Safety Science.

Languages :

- English

This role offers hybrid flexible working requiring approx. 2 days a week based in office

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>

Commitment to Diversity & Inclusion:

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

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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>

División

Development

Business Unit

Innovative Medicines

Ubicación

Irlanda

Sitio

Dublin (NOCC)

Company / Legal Entity

IE02 (FCRS = IE002) Novartis Ireland Ltd

Functional Area

Research & Development

Job Type

Part time

Employment Type

Regular

Shift Work

No

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