

Analyst - Patient Oriented Programs

Job ID
REQ-10006270

May 20, 2024

India

Summary

The primary responsibility of this role is to manage patient oriented program (POP). Responsible to ensure compliance in POP end to end activities as per the applicable process and quality standards. Liaison with the cross functional team for successful execution of POP.

About the Role

Analyst Patient-Oriented Program

Location - Hyderabad #LI Hybrid

About the Role:

The primary responsibility of this role is to manage patient oriented program (POP). Responsible to ensure compliance in POP end to end activities as per the applicable process and quality standards. Liaison with the cross functional team for successful execution of POP.

Key Responsibilities:

- Administer end to end POP process on behalf of Business Owner (BO) in accordance with Doing Business Ethically (DBE) policy and POP Standard Operating Procedures (SOP).
- Coordinate with all POP stakeholders (POP Champion/ Procurement/ Legal/ Patient Safety/ Compliance/Quality Assurance) and create POP documents.
- Responsible for obtaining the necessary approvals for conduct of POP in a timely manner. Responsible for the overall management of the External Service Providers (ESP) compliance check prior to fieldwork initiation.
- Enter program details in the POPsys database throughout the conduct of the POP. Keep track of all required activities (First Participant First Contact (FPFC)/Last Participant Last Contact (LPLC) dates, Adverse Event Reconciliation (AER), Periodic Reviews, closure, etc.) related to POP conduct and ensure no monitoring gaps before program closure in POPsys.
- Maintain documentation for all POP related activities in POP repository. Ensure identified quality issues are well documented in quality issue (QI) management tool. Create issue record and perform proper investigation, root cause analysis followed by risk assessment and corrective and preventive actions (CAPA).
- Ensure proper handover of activities when leaving the role/organization/planned leaves and liaise with POP Champion. Effective management of all projects assigned, and timely escalation of findings related to projects. Seek constant feedback from stakeholders and improve on suggestions put forth.

Essential Requirements:

- Preferable experience with 2- 5 years ' experience in the pharmaceutical industry within Clinical, Pharmacovigilance (PV), Medical/regulatory Affairs, or relevant experience in pharma compliance or commercial framework.
- Good understanding of local regulatory requirements and applicable policies surrounding pharmaceutical industry
- Ability to communicate effectively across different audiences, organizational levels and local and global teams.

Desirable Requirements:

- College/university degree, preferably in security, criminal justice, crisis management, business continuity or other related field. Advanced degree is highly desirable (e.g., Master ' s degree or MBA).

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部門
Operations

部門
CTS

国
India

勤務地
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Marketing

職種
Full time

雇用形態
Regular

Shift Work
No

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