

PSP specialist

Job ID
REQ-10015353

7月 23, 2024

South Korea

摘要

• Responsible for the overall management and compliance of his/her respective Patient Support Programs (PSPs) according to Novartis global and local procedures, Good Documentation Practices and Health Authority regulations.

About the Role

Internal Role Title: PSP Specialist (Patient Support Programs)

Location: Seoul, Korea #LI-Hybrid

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Key Responsibilities:

- Responsible for the design, planning and conduct of PSP, ensuring resource and time allocation for completing all activities:
 - Co-ordinate with all PSP stakeholders (POP Champion/ Procurement/ Legal/ Patient Safety/ ERC), as appropriate
 - Responsible for obtaining the appropriate approvals (ERC and POPsys) for conduct of PSP in a timely manner
 - Responsible for the overall management of the External Service Provider (ESP)/Healthcare Professional (HCP), being the main point of contact and ensuring the following activities are completed prior to the beginning of ESP services
 - conduct of POP Supplier Quality Assessment (SQA) and other supplier qualifications (Information Security and Risk Management (ISRM)/Third-Party Assessment Service (3PAS), Anti-Bribery), as applicable
 - contract execution, including Pharmacovigilance and data privacy language, and ESP AE training
 - In collaboration with the Source Data Verification Responsible (SDVR), responsible for identifying source documents and ensuring they are clearly communicated to the ESP/HCP and local POP stakeholders.
 - Enter program details in the POPsys database throughout the conduct of the PSP
 - Ensure required data is obtained to conduct monitoring activities (Adverse Event Reconciliation (AER) and Source Data Verification (SDV))
 - Keep track of all required activities (FPFC/LPLC dates, AER, SDV, closure, etc.) related to PSP conduct and ensure completion before program closure in database
- Regularly interact with the POP Champion and the Pharmacovigilance Responsible (PVR) to discuss PSP and ESP performance and compliance, and collaborate with them to actively follow-up on cases of non-compliance, including late AE reporting, and to ensure appropriate action and risk mitigation (deviations and CAPAs)
- Ensure compliance with all local laws and regulations
- Support during internal/external audits and inspections as needed
- Ensure proper handover of activities when leaving the role/organization/planned leaves and liaise with POP Champion as required
- Develop program materials for PSP based on approved scheme and ensure them in compliance with company guidance.
- Maintain and file relevant key documents including G-folder and hardcopy files with each event master binder (e.g. approval form, minutes, signed contract, vendor QC, etc.)
- Manage and evaluate vendor based on KPIs mentioned in contract
- Execute financial and legal activities (development of contract, review process via CLM, payment via SRM) in accordance with internal procedure.

Essential Requirements:

- Relevant experience with Customer service
- Cross-functional collaboration experience
- Adaptability to new technology and challenge-oriented with passion and confidence
- Solid understanding of patient and hospital environment

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部门

Corporate Affairs

Business Unit

Innovative Medicines

地点

South Korea

站点

Seoul

Company / Legal Entity

KR01 (FCRS = KR001) Novartis Korea Limited

Functional Area

Communications & Public Affairs

Job Type

Full time

Employment Type

Regular

Shift Work

No

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