NOVARTIS

PSP specialist

Job ID
REQ-10015353
Jul 23, 2024
South Korea

Summary

• Responsible for the overall management and compliance of his/her respective Patient Support Programs (PSPs) according to Novartis global and local procedures, Good Doc-umentation 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

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

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Division
Corporate Affairs
Business Unit
Innovative Medicines
Location
South Korea
Site
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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