

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

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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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Novartis is an Equal Opportunity Employer and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

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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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