【800～1200万円】Safety Specialist

安全性情報（臨床開発・製販後GVP）のご経験のある方は歓迎です。

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
非公開

Job ID
1568366

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
8 million yen ~ 12 million yen

Holidays
【有給休暇】最大20日（入社月に応じて変動あり） 初年度 10日 1か月目から 【休日】完全週休二日制 祝日 夏季休暇 年末年…

Refreshed
January 8th, 2026 18:00

General Requirements

Career Level
Mid Career

Minimum English Level
Fluent

Minimum Japanese Level
Native

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

【求人No NJB2344966】
■Primary Purpose / Regulatory Responsibilities:
Collaborate with the Process Management Team members and the Product Management Team members to ensure Safety communication and product stewardship
・ Ensure Pharmacovigilance systems operations and procedures are in place within the local organization for all territories assigned to the Affiliate
・ Key Contributor within the broader Patient Safety and/or Development Japan

■MAJOR RESPONSIBILITIES

Pharmacovigilance System
・ Ensure that the required local information for the Pharmacovigilance System Master File （PSMF） is made available to the EEA QPPV office either directly or through local delegations （The company colleagues or third parties）
・ Implement and maintain a pharmacovigilance system for The company products authorized in the territory and ensure compliance with applicable regulatory and company requirements
・ Work in close collaboration with corporate Patient Safety teams to ensure that local obligations are managed and compliance with local authorities is maintained
・ Provide input into global/local processes to secure compliance
・ Maintain quality management system related to the pharmacovigilance including management of Standard Operating Procedures （SOPs） Associated Instructions （AIs） and documents （e.g. forms templates） to describe local processes and requirements and perform regular gap analysis as needed in order to ensure alignment with global SOPs
・ Maintain oversight of local deliverables delegated to service providers
・ Ensure timely management of deviations and risk mitigation by defining appropriate CAPAs and ongoing trend analysis as appropriate.
・ Identify plan and implement key projects to improve quality reduce costs and increase productivity by reducing wasted time scrap rework etc. resulting in significant business improvement

Patient Support Programs/Market Research programs/Digital initiatives
・ Collaborate in true partnership with business units in programs leading to solutions for patients plus ensure compliant set up and oversight
・ Proactive assessment of the capability and capacity of PSP/MRP vendors to conduct critical pharmacovigilance tasks （in support of qualification audits） and avoid issues of regulatory compliance

Proactive Regulatory Intelligence
・ Maintain thorough knowledge of the local current pharmacovigilance regulatory requirements and landscape plus proactively monitor for emerging regulations and communicate such to corporate teams （including EEA QPPV） local stakeholders
・ Perform Impact assessment gap analysis and implementation strategy for new or updated regulations and notify the EEA QPPV corporate Patient Safety and relevant stakeholders.

Health Authority inspections and Audit readiness
・ Ensure inspection and audit readiness of the relevant local departments in full collaboration with corporate Patient Safety and Quality Assurance
・ Participate in and manage pharmacovigilance audits and inspections perform root cause analysis ensuring timely identification and implementation of respective Corrective Actions Preventive Actions （CAPAs）

Product Stewardship
・ Ensure that all information relevant to the benefit/risk balance of The company products is reported to Patient Safety （including the EEA QPPV for products authorized in the EEA） for further review and to the competent authorities according to the local pharmacovigilance legislation
・ Provide input into the Risk Management Strategy as needed to secure local compliance
・ Act as local Subject Matter Expert on product safety contributing to the product lifecycle activities product information （e.g. labelling review） and risk management e.g. recalls DHCP letters implementation of Risk Management Plan as applicable
・ Participate contribute in product launch strategic meetings and ensure implementation of safety reporting related activities such as vendor qualifications GxP assessments training etc.

Stakeholder Management
・ Engage in transversal collaboration with affiliate and corporate stakeholders to secure pharmacovigilance compliance
・ Engage external stakeholders e.g. scientific community patient advocacy groups regulators and pharma industry for insights that lead to solutions for patients
・ As a team member to ensure that Pharmacovigilance systems operations and procedures are in place within the local organization for all territories assigned to the Affiliate Japan

Required Skills

■EDUCATION QUALIFICATION
・Bachelor's Degree
・HCP based education （e.g. physician pharmacist nurse） or any relevant graduation/experience in medical scientific area e.g. PhD/Master in biological sciences or related degree）

Company Description

ご紹介時にご案内いたします