【800 ~ 1270万円】Safety Specialist

外資製薬メーカーでの募集です。 安全性情報（臨床開発・製販後GVP）のご経験の...

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
外資製薬メーカー

Job ID
1598240

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
8 million yen ~ 12 million yen

Holidays
詳細は求人ご紹介時にご案内いたします。

Refreshed
June 25th, 2026 16:57

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 NJB2391092】
JOB SUMMARY
Primary Purpose / Regulatory Responsibilities:
・ Responsible for ensuring Pharmacovigilance systems operations and procedures are in place within the local organization for all territories assigned to the Affiliate as delegated
・ Back up（or primary when delegated）contact for pharmacovigilance at the Affiliate
・ Support the operational management of 1 2 medium or 1 highly complex Affiliate/country
MAJOR RESPONSIBILITIES
Support the Local Safety Officer to ensure oversight and management of Affiliate PV responsibilities as delegated/applicable:
Pharmacovigilance System

・ Implement and maintain a pharmacovigilance system for the products authorized in the territory and ensure compliance with applicable regulatory and company requirements;
・ Identify and clearly articulate evolving local needs（ regulation changes eco system changes etc. ） impacting Pharmacovigilance and as required work collaboratively with corporate Pharmacovigilance teams to develop and implement solutions; Provide input to harmonize global/local processes and to secure compliance; Work in close collaboration with corporate Pharmacovigilance teams to ensure that local obligations are managed and compliance to local authorities is maintained and secured;
・ Maintain quality management system related to 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.
・ Maintain a functional connection with the Qualified Person for Pharmacovigilance（ Global/EEA QPPV ） e.g. participating in regular Local Safety Officer（ LSO ） meetings organized by corporate Pharmacovigilance;
・ 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（ colleagues or third parties ）;
・ Ensures that adequate back up processes are available
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 Global/EEA QPPV（ as applicable ） corporate Pharmacovigilance and relevant stakeholders.
Health Authority inspections and Audit readiness
・ Ensure inspection and audit readiness of the relevant local departments in full collaboration with corporate Pharmacovigilance 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 ）;
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 leads to solutions for patients.
Other accountabilities for the role may include some or all the tasks responsibilities such as ・
・ Support the LSO in operational management of 1 2 medium or 1 high complexity Affiliate/country.
・ Collaborate as Deputy LSO for another country outside of direct Affiliate responsibility or another Affiliate as applicable
・ Act as back up SME for other Affiliates/countries
・ Support effective smooth management of Partnerships/vendors additionally for at least 1 countries/Affiliates

Required Skills

■EDUCATION QUALIFICATION
Bachelor's Degree

Other : HCP based education（ such as physician pharmacist nurse ） or any relevant graduation/experience in medical scientific area（ such as PhD/master in biological sciences or related degree ）

■COMPETENCIES
Specific skills
・ Expert in pharmacovigilance with an in depth expert knowledge of associated regulatory requirements;
・ Ability to plan organize prioritize and execute multiple tasks within assigned objectives to meet compliance requirements;
・ Have good interpersonal skills ability to work independently in matrix organizations;
・ Team working and networking promoter;
・ Qualities of authenticity resilience and adaptability;
・ Communicates personal views clearly even if they may be opposed by others;
・ Be a Role model with high level of integrity and honesty both internally and externally. Ability to inspire peers stakeholders and others;
・ Excellent oral and written communication skills as the position requires to interact across multiple levels and with diverse functions（ e.g. commercial quality regulatory legal medical ） within and outside UCB（ e.g. regulators patients HCP’s Pharma industry associations ）;
・ Excellent verbal and written communication in English and local language as required（ specify any local language skills according to local requirements if any ）;
・ Good meeting preparation facilitation skills
・ Demonstrated ability to understand analyze and summarize scientific and medical information;
・ Professional demeanor team orientated self motivated and ability to effectively engage with stakeholders;
・ Problem solving:
a ） Experience and ability to identify risks or issues propose solutions or alternatives; Ability to identify gaps perform trend analysis and implement risk mitigation strategy
b ） The Ability to understand and use technology knowing its limitations and understanding the risks and the precautions that usage requires

Company Description

ご紹介時にご案内いたします