

【800 ~ 1400万円】Sr. Manager Patient Safety

ルンドベック・ジャパン株式会社での募集です。 安全性情報（臨床開発・製販後GV...

募集職種

人材紹介会社
株式会社ジェイ エイ シー リクルートメント

採用企業名
ルンドベック・ジャパン株式会社

求人ID
1619906

業種
医薬品

会社の種類
外資系企業

雇用形態
正社員

勤務地
東京都 23区

給与
800万円 ~ 1400万円

勤務時間
09:00 ~ 17:30

休日・休暇
【有給休暇】年間有給休暇：入社月により変動 【休日】完全週休二日制 土 日 祝日 年末年始（12/29 1/3）、傷病休暇 ※...

更新日
2026年11月26日 06:00

応募必要条件

キャリアレベル
中途経験者レベル

英語レベル
ビジネス会話レベル

日本語レベル
ネイティブレベル

最終学歴
大学卒： 学士号

現在のビザ
日本での就労許可が必要です

募集要項

【求人No NJB2400333】
Purpose of the job:
This role is a critical addition to Lundbeck Japan's Drug Development organization reporting to the Head of Patient Safety Japan. The individual will serve as a senior pharmacovigilance professional responsible for supporting the safety oversight of Lundbeck's expanding product portfolio in Japan including both marketed products and pipeline assets approaching regulatory milestones. The role is positioned at a level where the successful candidate would be expected to develop toward

readiness for broader safety responsible leadership including eligibility for the Deputy Anseki designation under the PMD Act and J GVP regulations. This requires someone who combines deep pharmacovigilance expertise with the independence judgment and collaborative approach needed to contribute meaningfully in a lean and growing organization.

Responsibilities:
・ Serve as the primary backup to the Head of Patient Safety Japan including acting as Deputy Anseki when required.
・ Exercise independent and accountable judgment on safety related matters in accordance with Japan regulatory requirements global pharmacovigilance standards Anseki’s direction. and company strategy.
・ Provide safety oversight across Lundbeck Japan's portfolio including marketed products and clinical stage assets ensuring compliance with J GVP and applicable global pharmacovigilance regulations.
・ Manage and oversee relationships with external vendors responsible for case processing safety database operations and related outsourced pharmacovigilance activities ensuring contractual compliance data quality and timely regulatory reporting.
・ Maintain and oversee safety operational process governance including the maintenance of local QMS documents and Pharmacovigilance agreement（PVA）or Safety Data Exchange Agreements（SDEAs）with third parties .
・ Contribute to the establishment and maintenance of Japan Risk Management Plans（J RMPs）including risk minimization strategies and Early Post marketing Phase Vigilance（EPPV）activities for new product launches collaborating with global and local stakeholders.
・ Interface with the PMDA on safety related matters including support for regulatory inspections GVP self inspections and responses to regulatory inquiries.
・ Collaborate with global Patient Safety counterparts to ensure alignment on signal detection benefit risk assessment aggregate reporting and safety data exchange.
・ Partner cross functionally with Clinical Development Regulatory Affairs Product Quality and Medical Affairs to ensure integrated safety input across development and commercial activities.
・ Provide scientific and strategic input on safety related components of regulatory submissions in collaboration with global Patient Safety including contributions to J NDA safety sections J DSURs J PSURs and re examination dossiers.
・ Identify and drive continuous improvement in pharmacovigilance systems within the Japan Patient Safety function.

Tasks:
・ Provide managerial oversight of pharmacovigilance operations as Deputy Anseki when required including supervision of team activities and end to end oversight of safety processes to ensure regulatory compliance quality and operational effectiveness.
・ Conduct review and quality oversight of Individual Case Safety Reports（ICSRs）from both post marketing and clinical trial sources in accordance with Japan regulatory requirements ensuring accuracy completeness and appropriate judgement.
・ Prepare review and ensure timely submission of periodic safety reports（J PSURs J DSURs）and annual infection reports as required.
・ Develop and maintain inspection readiness documentation and support the execution of internal self inspections and external regulatory audits.
・ Establish and manage post marketing safety activities（including postmarketing surveillance clinical research market research and patient support programs）in compliance with pharmacovigilance requirements in collaboration with relevant internal functions and vendor staff.
・ Support launch readiness activities for new products by contributing to safety planning and EPPV design.
・ Monitor regulatory developments and evolving PMDA expectations related to pharmacovigilance and drive operational or procedural adjustments.

スキル・資格

Education / Certifications:
・ Bachelor's degree in pharmacy life sciences nursing public health or related field required. Advanced degree（MSc PhD PharmD）preferred.
・ Good Clinical Practice（GCP）and Good Vigilance Practice（GVP）training.

Experiences
・ Minimum 10 years of pharmacovigilance experience in the pharmaceutical or biotechnology industry with substantial exposure to Japan specific PV regulations（GCP GVP）.
・ Demonstrated experience interacting with the PMDA and supporting regulatory inspections.
・ Proven track record in managing outsourced pharmacovigilance operations including CRO/vendor oversight case processing quality management and PVA governance.
・ Experience contributing to or leading the preparation of J RMPs aggregate report including J DSURs J PSURs re examination dossiers and safety sections of regulatory submissions.
・ Strong understanding of global pharmacovigilance frameworks（ICH EU GVP）and how they interface with Japanese requirements.
・ Prior experience in a Deputy Anseki or equivalent safety responsible backup role is strongly preferred.
・ Experience supporting safety operations during product launches including EPPV and post marketing surveillance（PMS）is a distinct advantage.

Competencies:
・ Regulatory and Scientific Expertise: Deep working knowledge of GVP GCP and global pharmacovigilance regulations combined with the ability to interpret and apply complex regulatory requirements in practical operational contexts.
・ Oversight and Process Thinking: Strong orientation toward process governance vendor management discipline and continuous improvement in how pharmacovigilance operations are structured and executed.
・ Curiosity and Strategic Maturity: Demonstrates an open minded approach to emerging and evolving situations and actively explores how Patient Safety can contribute. Ability to think beyond day to day operations and contribute to the broader strategic direction of the Patient Safety function with the judgment and confidence to serve as a credible sparring partner to the function head.
・ Flexible mindset: Demonstrates a flexible mindset with the ability to generate multiple approaches to demonstrating compliance with both Japan and global requirements and to make optimal situation appropriate judgments.

・ Independence and Accountability: Capable of operating with limited supervision taking ownership of deliverables and making sound decisions under time pressure
in a organizational environment.
・ Cross functional Collaboration: Effective at working across functional boundaries with Clinical Development Regulatory Affairs Product Quality and Medical Affairs and across organizational boundaries with global Patient Safety counterparts.
・ Communication: Strong written and verbal communication skills in both Japanese and English with the ability to present complex safety information clearly to internal stakeholders and regulatory authorities.

会社説明

医薬品輸入販売