

Patient Safety (GVP), Senior Manager

募集職種

人材紹介会社
株式会社 JAC International

採用企業名
Global European Pharmaceutical Company (Small Sized)

求人ID
1617183

業種
その他

雇用形態
正社員

勤務地
東京都 23区

給与
経験考慮の上、応相談

更新日
2026年10月29日 21:00

応募必要条件

職務経験
3年以上

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
ビジネス会話レベル

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

About the job
Purpose of the job:
This role is a critical addition to 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 our 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 our 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.

Employee Benefits:
Employment Type: Full Time Employee
Office Location: Tokyo
Working Style: Hybrid
Salary Range: 10~15mil annual total
Welfare and Benefits: All Included and comprehensive plan.
Interview Steps: 3
Working Language: Japanese and English

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 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

新たに日本マーケットに参入される外資系企業や、日本でさらなるビジネス拡大をお考えの外資系企業のお客様に、私たちは最適な採用サポートを提供いたします。1975年に英国初の日系人材紹介会社としてロンドンで創業し、その後シンガポール、日本、マレーシア、インドネシア、タイ、中国の7カ国 (また2011 年には香港・韓国にも拠点を新設予定) でグローバル人材紹介会社として事業を拡大してきたジェイ エイ シーは、そのバックグラウンドから、海外文化への深い理解を持ち合わせています。グローバルに事業を展開する日系人材紹介会社のリーディングカンパニーとして、私たちは他に類のない人材ネットワークから、日本人の優秀なバイリンガル人 材や外国人のプロフェッショナル人材をご提供することが可能です。幅広い業種、職種においてのエキスパートである当社のネイティブあるいはバイリンガルコ ンサルタントが皆様のパートナーとなり、適材適所で人材のご紹介をいたします。ジェイ エイ シーが築いてきた特有の歴史、文化、そしてグローバルマーケットでの強みを揺ぎない核として、日本マーケットで躍動する外資系企業のお客様のニーズにさら に的確にお答えするために、ジェイ エイ シー インターナショナルは誕生しました。私たちはアジアやヨーロッパのJAC Recruitment Group海外各社と緊密に連携を取り、お客様の真のニーズを把握した上で、最適なキャンディデイトをご紹介いたします。

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We provide specialized proactive recruitment support tomultinational clients who are setting up new operations or areexpanding existing business and seeking further growth in theJapanese market.As the first Japanese recruitment company to set up operations in theUK in 1975, understanding foreign cultures is second nature to us.With our extensive global network and historically leading position asrecruitment consultancy to Japanese corporations, we have access toan unrivaled pool of bilingual Japanese and foreign professionals.Our professional consultants are experts in a range of Industries andfunctions and all have extensive multicultural experience.Based on JAC’s unique history, culture and market strength, JACInternational was founded to provide dedicated support to ourmultinational corporate clients in Japan.

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