【1150 ~ 1400万円】【R D】Patient Safety Epidemiologist 研究開発本部 ペイシェント …

アストラゼネカ株式会社での募集です。 安全性情報（臨床開発・製販後GVP）のご…

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
アストラゼネカ株式会社

求人ID
1586961

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
1100万円 ~ 1400万円

勤務時間
09:00 ~ 17:15

休日・休暇
【有給休暇】入社7ヶ月目には最低10日以上 【有給休暇】※入社月により付与日数が異なります。詳細はオファー時に通知いたします …

更新日
2026年05月30日 14:00

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

最終学歴
大学院卒： 修士号/博士号

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 NJB2370625】
■職務内容
Description:
The PS Epidemiologist（PSEPI）serves as a study lead for Post Authorization Regulatory Commitment Studies（PARCS）including post marketing database study and use result survey accelerating the generation of valuable real

world evidence. Leveraging extensive clinical research expertise including secondary data analysis as well as various data assets and access rights held by AZKK the PSEPI is responsible for the methodological reliability and scientific robustness at all stages of responsible research from study planning and execution to study completion and publication. As an expert in epidemiological research the PSEPI leads the education and utilization of real world data within the Japan Patient Safety organization and contributes to organizational development.

Accountabilities/Responsibilities:
Strategic Evidence Planning
PSEPI contributes to the development of local Risk Management Plans（RMPs）preparing by Japan Patient Safety（PS）. They start planning formulate Pharmacovigilance Plan（PVP）strategies and PARCS from the preparation stage of the new drug application（NDA）and lead discussions and consensus building with internal stakeholders and regulatory authorities regarding PVP strategies for NDAs.

Study Execution
PSEPI creates study design concepts（SDC）and clinical study protocols（CSP）based on PVP strategies as the scientific lead for PARCS. They conduct feasibility assessments for PARCS and lead the technical review and approval of SDC/CSPs within the global governance related to evidence generation. In study execution and publicizing study results the PSEPI leads regulatory processes including epidemiological consultations and engages with internal and external stakeholders. They oversee the execution of the analysis plan and the preparation of interim and final reports with study team members ensuring quality by reviewing deliverables. They also support the planning and execution of external presentations and publication.

Leading team as an epidemiologist
In team working the PSEPI serves as the leader of cross functional study teams leveraging members' expertise to ensure the successful execution of study activities. They provide coaching to study team members to support and accelerate their performance and facilitate smooth collaboration with cross functional company wide teams as a representative of Japan Patient Safety. As a skills leader the PSEPI contributes to enhancing the real world evidence（RWE）generation capabilities of PS Epidemiology Evidence Generation members. They monitor changes in the external environment related to epidemiological research methodologies available information sources research related technological trends regulatory trends and guidance on evidence generation in therapeutic areas and lead the continuous improvement of deliverable quality by integrating these changes into company processes.

スキル・資格

◆ 必須条件（Mandatory）
経験
'・Practical experience in pharmacoepidemiology research within a pharmaceutical company academia or CRO（approx. 2+ years for PhD holders or 5+ years for Master’s holders）.
・Experience authoring and reviewing protocols and Clinical Study Reports（CSRs）for observational studies（e.g. comparative effectiveness or safety studies）.
・Experience conducting database studies（DB studies）including a deep understanding of the characteristics of Japanese claims data DPC data and electronic medical record（EMR）data.
・Experience in conducting meetings discussions and consensus building in English with global teams（e.g. HQ functions）demonstrating the ability to hold verbal discussions beyond email correspondence.

資格
・ MPH or MSc with equivalent experience in pharmacoepidemiology epidemiology or related health science field.

能力
・Cross functional Leadership: Demonstrated leadership and ability to influence without authority to facilitate cross functional collaboration（e.g. Development Medical Regulatory Patient Safety）and drive teams toward common goals in complex environments.
・Vendor Management: Ability to effectively manage external partners（CROs data providers academia）including selection contracting and oversight of quality and timelines to maximize performance.
・Process Optimization: Ability to identify operational issues and drive improvements in productivity and quality through the development of Standard Operating Procedures（SOPs）and workflow optimization.
・Ethics: Overriding commitment to integrity high ethical standards and compliance in all professional activities.

語学
日本語 Japanese：ネイティブ
英語 English Business English Level（Globalとの会議の中で発言・議論することが必要）

◆ 歓迎条件（Nice to have）
経験
・Hands on analysis experience using statistical software such as SAS R or SQL（or experience providing detailed instructions to and reviewing the work of programmers/statisticians）.
・Experience as a lead author in publishing papers in peer reviewed international journals and presenting at academic conferences.

資格
・ Ph.D. in pharmacoepidemiology clinical epidemiology or related health science field.

能力
・Regulatory Knowledge: Solid working knowledge of Japanese regulatory requirements（J GPSP GVP）and relevant guidelines applicable to the planning and execution of pharmacoepidemiology studies and post marketing surveillance.
・Cost effectiveness Budgeting: Ability to plan and manage project budgets and optimize resource allocation. Or the ability to propose strategies with a perspective on cost effectiveness to maximize the value of research outcomes.
・Drug Development Knowledge: Broad knowledge of drug development and lifecycle management（LCM）.

会社説明

医療用医薬品の開発、製造及び販売