【1100～1550万円】※11/21応募締め切り【GBS PS】Local Case Intake Team Manager

アストラゼネカ株式会社での募集です。 臨床開発リーダー・臨床開発プロジェクトマ...

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
1566736

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
大阪府

給与
1100万円 ~ 1500万円

勤務時間
09:00 ～ 17:15

休日・休暇
【有給休暇】有給休暇は入社時から付与されます 【有給休暇】 初年度 4～16 日 （ 1 か月目～ ） 入社月により付与日数が...

更新日
2026年01月08日 20:00

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 NJB2338248】
The Core responsibilities include:

Maintain in depth knowledge of the local health authority regulations and update local teams with any new changes in legislation/guidance for discussion and escalation to relevant stakeholders in Global Patient Safety as required.

Ensure that local procedural documents/ standard operating procedures are followed for reporting/processing/ translation of AEs and are up to date available for any patient safety audit and inspection.

Support where necessary local maintenance activities relating to the Pharmacovigilance System Master File （PSMF）

Maintain oversight of all patient safety related processes for Japan regulatory reporting

Maintain current knowledge of the marketed status of products in the local country and reference documents （such as Product Information/Datasheet）

Support full and prompt response to any patient safety query from the local regulatory authority related to patient safety function as determined by GBS and AstraZeneca agreed KPIs and SLAs

Participate in audits and inspections ensuring the local case intake process is audit ready

Facilitate the necessary quality including correctness and completeness of PV data submitted to the local regulatory authority

Support local safety management agreements to fulfil AstraZeneca and local regulatory safety reporting requirements

Ensure cross function collaboration through sharing patient safety knowledge with the Japan MC teams （e.g. Japan Patient Safety Sales Regulatory Affairs Medical Affairs; refer to Key Relationships to Reach Solutions）

Ensure timely submission of ICSR follow up cases and other safety documents to local health authorities

Ensure corrective and preventative actions are taken in the event of local non compliance or breach of agreed SLAs.

If required support review of medical and scientific literature to identify possible Adverse events in accordance with AstraZeneca and local regulatory pharmacovigilance requirements

Establish strong relationships and effective cross function collaboration with regulatory marketing medical and other internal and external stakeholders' functions to deliver patient safety requirements for business and regulatory needs （refer to Key Relationships to Reach Solutions）

Ensure that the local case intake team completes all required patient safety training Global and local PS systems （e.g. Argus） and adheres to internal processes and external regulations.・ Act as a mentor to support newly appointed Case Intake Advisors

Ensure an after hours process is in place and maintained to ensure a customer can report an AE and respond to regulatory authority questions

Oversee filing and archiving practices of patient safety documents

Manage patient safety compliance data for the case intake team is up to date （e.g. monthly）

Ensure appropriate Local Case Intake Advisor cover is in place so that all activities continue to be performed within the required timeframes when out of the office on holiday unexpected leave etc

Support patient safety projects at local global levels

Leading the reporting and investigation of any quality incidents related to processes within the local case intake team

Performs other related duties as assigned or requested per business needs

Training and mentoring of staff on safety information pertaining to Intake Literature reports and regulatory reporting processes

Review and/or creation of metrics to measure intake and reporting compliance to regulatory agencies Alliance Partners internal destinations

Ensure delivery of services meets or exceeds Service Level Agreements through focused metrics management of process performance

Generate reports use Management Information System and/or provide updates on service delivery employee engagement process improvements etc. for timely reporting and enable decision making

スキル・資格

Requirements

Essential

Degree Qualified ・ Pharmacy/ Medical/ Science・

Thorough knowledge and experience of pharmacovigilance within the pharmaceutical industry・

Thorough knowledge of the current pharmacovigilance and regulatory developments・

Ability to work in a fast paced environment and meet tight deadlines

Excellent leadership and team management skills with the ability to motivate and develop staff in a multicultural environment

Experience in working cross functionally・・

Ability to set and manage priorities resource goals and project initiatives

Ability to influence strategically to obtain desired outcomes while maintaining effective positive organisational relationships

Excellent attention to detail・

Excellent written and verbal communication skills

Japanese language proficiency Test （JLPT）: N2 or higher・

English language proficiency: B1 Threshold based on Common European Framework Reference for Languages （CEFR）

会社説明

医療用医薬品の開発、製造及び販売