

求人情報

スタッフレベル

ポジション名	PV Specialist 大阪 / 東京
この求人情報の取扱い会社	マイケル・ページ・インターナショナル・ジャパン株式会社/Michael Page International Japan K.K.
企業名	会社名非公開
掲載開始・更新	2024-05-03 / 2024-05-03
職 種	メディカル/医薬/バイオ/素材/食品 - 臨床開発系
業 種	製薬メーカー
勤務地	アジア 日本 大阪府
仕事内容	<p>* Responsible for preparation and submission of expedited and periodic safety reports to Regulatory Authorities, Ethics Committees and Investigators, adhering to all data privacy guidelines, Good Clinical Practices (GCPs), Good Pharmacovigilance Practice (GVP), regulatory guidelines, company and project/program-specific procedures for clinical trials and/or post-marketing safety programs</p> <p>Description</p> <p>* Establish processes for and oversee the CRO's processing of individual case safety reports (ICSR)- including serious adverse event (SAE) reports and adverse events of special interest (AESI) reports- as well as distribution of safety information to appropriate internal and external parties according to local/international regulations within the specified timelines</p> <p>* Apply safety concepts (PMDA, ICH, JCP, and other international guidelines) to daily functions Oversee the CRO's data entry and administrative functions as required for the safety database Organize and coordinate regular internal safety review meetings, including working with clinical operations and biometrics to collate appropriate dataset; establish safety-related thresholds and metrics for ad hoc meetings</p> <p>* Participate in the development/revision of MedDRA Coding Conventions</p> <p>* Work with the project team to coordinate safety reporting processes between the PVG and Clinical CROs</p> <p>* Support the project teams in the preparation of all customized and other regulatory safety reports. (e.g., Developmental Safety Update Report (DSUR), cumulative SAE reports, safety database reports)</p> <p>* Assist in SAE reconciliation according to study requirements</p> <p>* In conjunction with ClinOps/QA/Regulatory, support the implementation of audit response plans</p> <p>* Contribute to the development and review of safety-related documents including study protocols, safety data collection forms & templates, case report forms, Investigator Brochures, and DSUR</p> <p>* Ensure coverage for SAE handling and other essential PVG functions during non-business hours, weekends, and holidays when required</p> <p>Profile</p> <p>*</p> <p>Experience in PV operations</p> <p>*</p> <p>Deep understanding of a series of PV operations, such as monitoring, triage, inputting, QC, and adverse event reports to local regulatory authorities</p> <p>*</p> <p>Able to perform PV operations independently without supervision</p> <p>*</p> <p>English ability to able to communicate effectively with global counterparts and sponsors</p> <p>*</p> <p>Experience in using safety databases such as Argus and Aris</p> <p>*</p> <p>Experience in PV input, evaluation and / or QC functions</p> <p>*</p> <p>Basic skills in Word, Excel and Outlook</p> <p>* Pharmacist, nurse, or other scientific experience is preferred</p>

	<p>Job Offer</p> <ul style="list-style-type: none"> * Opportunity to work on global PV and PMS studies * Work from home flexibility * Contribute to start up activities for Japan <p>Page Group Japan is acting as an Employment Agency in relation to this vacancy.</p>
企業について(社風など)	* Specialized global CRO delivering across more than 30 countries worldwide
勤務時間	Monday - Friday 09:00 - 17:00
英語能力	ビジネス会話 (TOEIC 735-860)
日本語能力	流暢 (日本語能力試験1級又はN1)
年 収	経験と能力に基づく