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Job Detail

Staff Level

Position Title	PV Specialist 大阪 / 東京
Recruiter Company	Michael Page International Japan K.K./マイケル・ペイジ・インターナショナル・ジャパン株式会社
Company Name	Company name is private
Activated / Updated	2024-05-03 / 2024-05-03
Job Type	Medical/Pharmaceutical/Bio/Fabric/Food - Clinical R & D
Industry	Pharmaceuticals
Location	Asia Japan Osaka
Job Description	* 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 Description * 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 * 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 * Participate in the development/revision of MedDRA Coding Conventions * Work with the project team to coordinate safety reporting processes between the PVG and Clinical CROs * 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) * Assist in SAE reconciliation according to study requirements * In conjunction with ClinOps/QA/Regulatory, support the implementation of audit response plans * 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 * Ensure coverage for SAE handling and other essential PVG functions during non-business hours, weekends, and holidays when required Profile * Experience in PV operations * Deep understanding of a series of PV operations, such as monitoring, triage, inputting, QC, and adverse event reports to local regulatory authorities

	* Able to perform PV operations independently without supervision * English ability to able to communicate effectively with global counterparts and sponsors * Experience in using safety databases such as Argus and Aris * Experience in PV input, evaluation and / or QC functions * Basic skills in Word, Excel and Outlook * Pharmacist, nurse, or other scientific experience is preferred Job Offer * Opportunity to work on global PV and PMS studies * Work from home flexibility * Contribute to start up activities for Japan Page Group Japan is acting as an Employment Agency in relation to this vacancy.
Company Info	* Specialized global CRO delivering across more than 30 countries worldwide
Working Hours	Monday - Friday 09:00 - 17:00
English Level	Business Conversation Level (TOEIC 735-860)
Japanese Level	Fluent(JLPT Level 1 or N1)
Salary	Depends on experience