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Job Detail

Staff Level

Position Title	Drug Safety Manager - EU Pharma
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	2024-05-02 / 2024-05-02
Job Type	Medical/Pharmaceutical/Bio/Fabric/Food - Clinical R & D
Industry	Pharmaceuticals
Location	Asia Japan Tokyo
Job Description	* Manage case processing activities and safety risk management for both investigational and marketed products, ensuring compliance with internal procedures and regulations Description * Manager of pharmacovigilance system in Japan including partnerships * Ensure full compliance with applicable pharmacovigilance regulations in Japan and with internal requirements Responsible * Support Clinical team for CTD submission and clinical trial management from a safety point of views as needs * Support to inspection and audit readiness of the affiliates in Japan in full collaboration with Patient Safety and pharmacovigilance QA * Evaluate ICRSs, literature, regulatory intelligence in foreign countries, and report to the local authority according to local regulations * Report all adverse event/reaction report (spontaneous Health Authorities, literature, etc.), to Global Patient Safety in timely manner * Evaluate the reportability and submit all qualifying case report and any new information relevant to the evaluation of the benefit/risk afforded by a product as required by local regulations and Global Patient Safety procedures Profile * Bachelor's degree, 3+ years of pharmacovigilance experience, knowledge of PV regulations and non-interventional studies, proficiency in English, and strong skills in safety information evaluation and collaboration. Job Offer * Work in an organization that values work/life balance, flexibility and career development * International career development possibilities in Japan and overseas Page Group Japan is acting as an Employment Agency in relation to this vacancy.
	* European bio-pharmaceutical company, with rich development pipeline in immunology, oncology and neurology areas *

Company Info	Our client is a leading player in the pharmaceutical industry, renowned for its commitment to innovation and patient care. With a global presence and a rich legacy of breakthroughs in healthcare, they offer an unparalleled opportunity for professionals seeking to make a real difference in people's lives. * At this dynamic organization, you'll be part of a team dedicated to advancing medical science and improving patient outcomes. From managing case processing activities to conducting safety risk management for cutting-edge compounds, every role here contributes to the development of life-changing therapies. * Joining our client means joining a culture of excellence and collaboration. You'll have the chance to work alongside industry experts, participate in high-level trainings, and contribute to the shaping of regulatory standards in pharmacovigilance. * Moreover, our client values talent and fosters a supportive environment for growth and development. Whether you're an experienced professional or just starting your career in pharmacovigilance, this is the place where your skills will be recognized, your ideas will be valued, and your career will thrive. * If you're passionate about making a meaningful impact in healthcare and seeking a stimulating and rewarding career opportunity, our client is the perfect place for you to grow and succeed.
Working Hours	Monday - Friday 09:00 - 18:00
English Level	Business Conversation Level (TOEIC 735-860)
Japanese Level	Fluent(JLPT Level 1 or N1)
Salary	JPY - Japanese Yen JPY 9000K - JPY 13000K