

## 求人情報

シニアレベル

ポジション名	Regulatory Operation Director at Global Leading Pharma
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	2024-05-02 / 2024-05-02
職 種	メディカル/医薬/バイオ/素材/食品 - その他 メディカル/医薬/バイオ/素材/食品 - 薬事申請/特許技術関連 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 東京都
仕事内容	<p>Take lead in regulatory submission activities for the business to get product approval. Be involved in publishing and archiving activities to ensure best practices.</p> <p>Description</p> <ul style="list-style-type: none"><li>* Lead in regulatory operations in submissions and being informed of up to date regulatory information to manage tracking systems</li><li>* Be the main point of contact in electronic submissions, including new data requirements tracking regulatory data for RIM system</li><li>* Create eCTD documents and electronic JNDA Data to the PMDA and other health authorities</li><li>* Manage any regulatory dossiers to align with regulatory operations</li><li>* Provide expertise in global SOPs in regulatory operations to relevant teams</li></ul> <p>Profile</p> <ul style="list-style-type: none"><li>* University degree in scientific or related fields</li><li>* High fluency in English and Japanese (Non-native level speakers will not be selected)</li><li>* Extensive experience in RA or regulatory operations in the pharmaceutical industry</li><li>* Knowledge of CTD/eCTD requirements to submit to health authorities</li><li>* Exposure in compiling/publishing to prepare for overseas submissions (ex. US/EU)</li></ul> <p>Job Offer</p> <ul style="list-style-type: none"><li>* Competitive salaries and benefits (potential RSUs)</li><li>* Great work life balance</li><li>* Global working environment</li><li>* Amazing career development in regulatory area</li><li>* Work with key leaders who are solving unmet medical needs</li></ul> <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)	<ul style="list-style-type: none"><li>* One of the top global patient-centric pharmaceutical companies in the industry</li><li>* Delivering cutting-edge therapies and products to patients with unmet medical needs</li><li>* Specializing in rare disease and orphan drug products with several blockbuster therapies out on the global market</li><li>* Global working environment with extensive communication with global stakeholders</li><li>* Hybrid style working style</li></ul>
英語能力	ビジネス会話 (TOEIC 735-860)
日本語能力	ネイティブレベル
年 収	日本・円 1100万円 ~ 1400万円