

Job Detail

Senior Level

Position Title	Regulatory Operation Director at Global Leading Pharma
Recruiter Company	Michael Page International Japan K.K./マイケル・ページ・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 - Other Medical/Pharmaceutical/Bio/Fabric/Food - Patent Medical/Pharmaceutical/Bio/Fabric/Food - Clinical R & D
Industry	Pharmaceuticals
Location	Asia Japan Tokyo
Job Description	<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"> * Lead in regulatory operations in submissions and being informed of up to date regulatory information to manage tracking systems * Be the main point of contact in electronic submissions, including new data requirements tracking regulatory data for RIM system * Create eCTD documents and electronic JNDA Data to the PMDA and other health authorities * Manage any regulatory dossiers to align with regulatory operations * Provide expertise in global SOPs in regulatory operations to relevant teams <p>Profile</p> <ul style="list-style-type: none"> * University degree in scientific or related fields * High fluency in English and Japanese (Non-native level speakers will not be selected) * Extensive experience in RA or regulatory operations in the pharmaceutical industry * Knowledge of CTD/eCTD requirements to submit to health authorities * Exposure in compiling/publishing to prepare for overseas submissions (ex. US/EU) <p>Job Offer</p> <ul style="list-style-type: none"> * Competitive salaries and benefits (potential RSUs) * Great work life balance * Global working environment * Amazing career development in regulatory area * Work with key leaders who are solving unmet medical needs <p>Page Group Japan is acting as an Employment Agency in relation to this vacancy.</p>
Company Info	<ul style="list-style-type: none"> * One of the top global patient-centric pharmaceutical companies in the industry * Delivering cutting-edge therapies and products to patients with unmet medical needs * Specializing in rare disease and orphan drug products with several blockbuster therapies out on the global market * Global working environment with extensive communication with global stakeholders * Hybrid style working style

English Level	Business Conversation Level (TOEIC 735-860)
Japanese Level	Native Level
Salary	JPY - Japanese Yen JPY 11000K - JPY 14000K

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