CareerCross

Manager Regulatory Affairs

株式会社ヴァンティブでの募集です。 薬事申請のご経験のある方は歓迎です。

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
株式会社ヴァンティブ

Job ID
1478848

Industry
Medical Device

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
7 million yen ~ 13 million yen

Work Hours
09:00 〜 17:30

Holidays
【有給休暇】初年度 10日 1か月目から 【休日】完全週休二日制 年末年始 特別休暇・慶弔休暇 【有給休暇】有り※詳細はオファ…

Refreshed
June 21st, 2024 22:00

General Requirements

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

【求人No NJB2205549】
■Role Overview
Registration and maintenance of Medical Devices

・Develop and execute regulatory plans aligned with business strategy for complex projects including new products and maintenance of regulatory files for existing marketed products

・Identify prioritize key areas of risk and develop implement appropriate mitigation plans
・Establish appropriate communication within RA with global Marketing and with other functions at project level and favor proactive communication
・Ensure Registration strategy and deliverables are aligned with project teams and business objectives
・Lead regulatory activities related to their portfolio of products
・Prepare review and approve labeling J CTD based on global dossier and in cooperation with PV/MDS and confirm sufficiency of total submission dossier package for approval
・Represent or lead the RA function on assigned cross functional project teams
・May participate external advocacy activity and contribute internal environment improvement
・May provide direct supervision of individuals
・Monitor applicable regulatory documentation and propose solutions. Identify areas for improvement
・Develop and document sound regulatory decisions and justification

Required Skills

■Qualifications ・ Scientific （Chemical） or Pharmaceutical background as well as regulatory knowledge ・ Experience of Medical Devices registration （minimum five years）. ・ English skills （TOEIC: above 700 or 800） strong written and verbal communication presentation skills

Company Description

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