CareerCross

【1020〜1440万円】Senior Regulatory Affairs Manager－IGTD

株式会社フィリップス・ジャパンでの募集です。 薬事申請のご経験のある方は歓迎で...

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
株式会社フィリップス・ジャパン

Job ID
1487820

Industry
Medical Device

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
10 million yen ~ 14 million yen

Work Hours
09:00 〜 17:30

Holidays
【有給休暇】有給休暇は入社時から付与されます 有給休暇:初年度最大20日間（入社月により変動） ※詳細はオファー時にご確認くだ...

Refreshed
August 1st, 2024 15:08

General Requirements

Career Level
Mid Career

Minimum English Level
Fluent

Minimum Japanese Level
Native

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

【求人No NJB2210881】
Exciting opportunity to lead Cardiac and Endovascular projects of Philips Image guided Therapy including novel technologies integrated by therapeutic devices and visualization systems.

・Develop local regulatory strategy and lead the strategic discussion with related stakeholders including Business Unit R D Clinical Affairs and Market Access Reimbursement to accelerate projects and fast serve patients.

・Proactively identify risks within regulatory strategies plans products and propose alternate approaches.
・Provide interpretation of local regulations to BU partners and ensure necessary requirements are fully deployed.
・Stay informed of new regulations and technologies relevant to endovascular therapeutics.
・Plan and execute product registration aligned with local business needs.
・Maintain current registration approvals accordingly.
・Manage interactions with MHLW/PMDA and maintain a productive working relationship.
・Review and Author product registration/reimbursement document.
・Proceed regulatory assessment and promotional material review.
・Oversee product registration and RA administration activities.
・Drive various transformation/improvement activities.

Required Skills

1. Experience.
+10 years' experience in medical device regulatory affairs
Actual experience of authoring Class III/IV medical device SHONIN submission in EVT or relevant devices and received approval.
Maintains extensive knowledge of PMD act ISO 13485.
Experience or working knowledge of active medical devices and imaging technologies.
Capable of resolving escalated issues arising from day to day operation.

2. Skills.
Self motivated and able to prioritize to handle multiple tasks/responsibilities.
Bachelor of Science Degree （Master preferred）
Fluent in Japanese and English

Company Description

医療機器、家電等の輸入販売。医療ITソリューション事業。