



Regulatory Affairs Manager

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

1488156

Industry

Medical Device

Company Type

International Company

Job Type

Permanent Full-time

Location

Tokyo - 23 Wards

Salary

7.5 million yen ~ 11 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さい...

Refreshed

January 17th, 2025 02:00

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 NJB2214555】

Your role:

Exciting opportunity to play an integral role in introducing new product/solution maintain regulatory compliance and leading transformation/improvement activities.

- Develop local regulatory strategy and lead the strategic discussion with related stakeholders to accelerate project development.
 - Proactively identify risks within regulatory strategies plans products and propose alternate approaches.
 - 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/Author product registration document and reimbursement document.
 - Proceed regulatory assessment and promotional material review.
 - Supervise RA administration activities.
 - Lead various transformation/improvement activities.
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Required Skills

1. Experience.

- +7 years' experience in medical device regulatory affairs
- Maintains general knowledge of PMD act ISO 13485 Radio act.
- Actual experience of authoring class III / IV medical device submission including SaMD and received approval.

2. Skills.

- Self motivated and able to prioritize to handle multiple tasks/responsibilities.
 - Bachelor of Science Degree in a technical discipline (Master's preferred)
 - Fluent in Japanese and English
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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。