



【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...

募集職種

人材紹介会社

株式会社ジェイ エイ シー リクルートメント

採用企業名

株式会社フィリップス・ジャパン

求人ID

1487820

業種

医療機器

会社の種類

外資系企業

雇用形態

正社員

勤務地

東京都 23区

給与

1000万円～1400万円

勤務時間

09:00～17:30

休日・休暇

【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...

更新日

2024年08月01日 15:08

応募必要条件

キャリアレベル

中途経験者レベル

英語レベル

流暢

日本語レベル

ネイティブ

最終学歴

大学卒：学士号

現在のビザ

日本での就労許可が必要です

募集要項

【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.
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スキル・資格

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

会社説明

医療機器、家電等の輸入販売。医療ITソリューション事業。