



【1200～万円】Regulatory Affairs

スペシャリティファーマでの募集です。薬事申請のご経験のある方は歓迎です。

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

スペシャリティファーマ

求人ID

1575845

業種

医薬品

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

1200万円～経験考慮の上、応相談

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 初年度：入社月により2～14日を付与（1か月目から） 【休日】完全週休二日制 土...

更新日

2026年02月21日 13:00

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 NJB2343210】

新薬承認申請業務

※詳細は担当者にご確認ください

スキル・資格

Who You Are:

Qualifications

- Bachelor's degree (scientific or clinical background desirable) required; advanced degree preferred.
- Minimum 7 years of Regulatory Affairs experience in the pharmaceutical or biotechnology industry required for Associate Director; Minimum 5 years of Regulatory Affairs experience for Senior Manager.
- Experience with managing CTN PMDA consultation and marketing authorization applications (e.g. J NDA) .
- Experience with preparation and review of electronic format (eCTD) submissions
- Direct interactions with PMDA/MHLW
- Experience in submission writing and review experience are essential.
- Experience with Orphan Designation and/or Expedited Programs for Serious Conditions (Designation of SENKUTEKI Iyakuhin Priority Review Designation etc.) preferred.
- Experience with post approval regulatory activities such as Japan Package Insert/MAH License maintenance etc. preferred.
- Must have ability to meet tight deadlines and be efficient detail oriented flexible and a self starter.
- Strong interpersonal skills to collaborate effectively across multiple functional areas.
- Excellent/business level communication skills in Japanese/English (verbal and written) .
- Highly organized with a strong attention to detail clarity accuracy and conciseness.
- A bias towards action combined with high ethical standards is essential.
- Initiative combined with a high energy level is critical to success.
- Must successfully exhibit Insmed's five (5) core corporate values of: Collaboration Accountability Passion Respect and Integrity; along with any other position specific competencies.
- Must demonstrate the ability to interact successfully in a dynamic and culturally diverse workplace.

会社説明

ご紹介時にご案内いたします