



【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。

Job Information

Recruiter

JAC Recruitment Co., Ltd.

Hiring Company

スペシャリティファーマ

Job ID

1575845

Industry

Pharmaceutical

Company Type

International Company

Job Type

Permanent Full-time

Location

Tokyo - 23 Wards

Salary

12 million yen ~ Negotiable, based on experience

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 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...

Refreshed

February 5th, 2026 16:05

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 NJB2343210】

新薬承認申請業務

※詳細は担当者にご確認ください

Required Skills

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.

Company Description

ご紹介時にご案内いたします