【1400～2000万円】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
1573260

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
14 million yen ~ 20 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 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
January 22nd, 2026 15:06

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 NJB2344821】
新薬承認申請業務
※詳細はお問合せください

Required Skills

Position Requirements: In the following categories indicate specific role requirements and qualifications that are absolutely necessary in order to perform the essential functions of the job.

Knowledge Experience
・Prior experience in gene therapy and/or orphan （rare） diseases in Japan strongly preferred. Strong working knowledge of biologic development within Japan is required
・Prior experience serving as the Japanese regulatory lead within a global matrixed organization
・Ability and experience in the development and execution of regulatory strategy in Japan
・In depth knowledge and direct application of Japan/International regulations regional and ICH guidance documents
・Regulatory writing and/or review of documents supporting product development and clinical trials in Japan
・Strong working knowledge and experience with electronic submissions （eCTD）

Qualifications
・Bachelor’s degree in scientific discipline required. Advanced degree in a scientific or regulatory discipline （Master's/PhD/PharmD） preferred.
・Minimum of 10 years of experience in Japanese Regulatory Affairs and/or relevant product development experience （biologics） within the pharmaceutical or biotechnology industry preferably with 5 7 years of gene therapy orphan （rare） drug development experience.
・Knowledge or direct experience of neurology and/or ophthalmology drug development is a plus
・Proven experience with initial CTN submissions and lifecycle maintenance ideally within the regenerative medicine space
・Prior experience in J NDA and CTx applications is desirable
・Prior experience leading direct interactions with PMDA/MHLW is required.

Skills
・Strong team player with the ability to collaborate effectively across multiple functional areas and Global regions
・Proven ability to lead cross functional initiatives and build effective partnerships
・Manage multiple priorities in a fast paced growing organization
・Exceptional written and verbal communication skills （English and Japanese） including regulatory writing
・Highly organized with a strong attention to detail clarity accuracy and conciseness

Other （if applicable）:
・Excellent planning and follow up skills
・Must be a self starter with the ability to be flexible to meet the business needs
・Computer proficiency with MS Office Suite programs Adobe Acrobat and Veeva Vault
・High ethical standards for compliance with regulations and procedures
・Initiative combined with a high energy level is critical to success
・Expected to exhibit Insmed’s five （5） core values of Collaboration Accountability Passion Respect and Integrity
・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