



【1400～2000万円】Director Clinical Pharmacology

Clinical Pharmacologyでの募集です。前臨床（薬効薬理・毒...

Job Information

Recruiter

JAC Recruitment Co., Ltd.

Hiring Company

Clinical Pharmacology

Job ID

1573257

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日～14日を付与 【休日】完全週休二日制 土日 祝日

Refreshed

January 22nd, 2026 15:06

General Requirements

Career Level

Mid Career

Minimum English Level

Fluent

Minimum Japanese Level

Native

Minimum Education Level

Post Grad Degree (PHD/MBA etc)

Visa Status

Permission to work in Japan required

Job Description

【求人No NJB2352009】

日本の規制当局対応を中心に、国内外の臨床薬理活動を科学的かつ規制面でリードします。

PK/PD評価や日本特有の規制要件に基づくフェーズI試験の設計支援、非臨床データの解釈、規制当局との交渉資料作成を担当。グローバルチームと密接に連携し、日本の規制要件を反映した開発計画を推進します。CRO管理や関連文書作成も担い、幅広い分子種の経験を活かして臨床薬理活動を統括。国内外の関係者と協働し、科学的整合性と規制対応の一体化を図ります。

Required Skills

■Experience / Knowledge

10+ years of experience in clinical pharmacology or PK/PD roles within the pharmaceutical industry PMDA or equivalent institutions.

Deep understanding of:

PK/PD principles

Japan specific clinical pharmacology data requirements

Japanese Phase I data requirements

Regulatory expectations for Phase I designs involving healthy Japanese subjects

Nonclinical PK/ADME interpretation and nonclinical - clinical bridging concepts

Experience preparing PMDA consultation materials and scientific justification packages.

Experience with CTD clinical pharmacology modules.

Demonstrated experience with both small and large molecule modalities (e.g. AAV antibodies protein therapeutics) is required to effectively support the Insmed portfolio as the sole CP representative in Japan.

■Skills / Capabilities

Strong PK/PD analytical and scientific communication skills

Ability to clearly explain CP and regulatory concepts to global stakeholders

High autonomy and flexibility

Strong cross functional and global teamwork skills

CRO/vendor management experience

Native level proficiency in Japanese is strongly preferred and business level proficiency in both written and spoken Japanese and English is required. The role requires the ability to actively participate in meetings clearly communicate complex concepts and engage in scientific discussions with global and Japan based stakeholders

■Qualifications

Advanced degree (PhD PharmD MS) preferred; bachelor's with extensive experience considered.

■Travels

Willingness and ability to travel approximately 10% (domestic and international) including overnight travel as required.

Company Description

ご紹介時にご案内いたします