CareerCross by JAC Recruitment

【1100～1600万円】【R D】Clinical Pharmacology （CP） Scientist Clinica…

アストラゼネカ株式会社での募集です。 前臨床（薬効薬理・毒性・ADME）のご経…

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
アストラゼネカ株式会社

Job ID
1514884

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
11 million yen ~ 16 million yen

Work Hours
09:00 ～ 17:15

Holidays
【有給休暇】入社7ヶ月目には最低10日以上 ※入社月により付与日数が異なります。詳細はオファー時に通知いたします
【休日】完全…

Refreshed
January 9th, 2025 16:50

General Requirements

Career Level
Mid Career

Minimum English Level
Business Level

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 NJB2270876】
Job Description
・ Contribute to regulatory events in Japan such as CTN PMDA consultation and JNDA
・ Contribute to Drug Metabolism and Pharmacokinetics （DMPK） and CP sections in the regulatory documents such as JCTD and JIB
・ Check the future submission package of DMPK and CP areas

・ Contribute to clinical studies AZKK implements e.g. inputting CP sections in CSP and CSR designing pharmacokinetic （PK） and pharmacodynamic （PD） assessments in clinical study
・ Propose potential strategies based on DMPK/CP profiles at JPT
・ Negotiate with PMDA on Japan development strategy and JNDA package

Accountability/Responsibility:
・ Responsible for initial assessment of DMPK/CP profiles of new candidates
・ Supports clinical options and strategies on Japan development program based on DMPK and CP profiles
・ Supports PK and PD components in clinical studies AZKK implements
・ Leads the CP/DMPK authoring in regulatory documents
・ Responsible for DMPK/CP inquiries at regulatory events in Japan
・ Responsible for Japan specific requirements on global DMPK/CP package including CTD
・ Supports the package inserts and interview form
・ Responsible for giving clear instructions to Career Level C staff on his/her task
・ Supports Career Level D staff on critical decisions on development strategy and regulatory interaction and accountable for the outputs
・ Leads research collaborations on CP/DMPK with academia and biotech/Pharmaceutical companies in Japan

Clinical Pharmacology Scientist directly reports to the Clinical Pharmacology Safety Science Director.

Required Skills

■経験 Experience
必須 Mandatory
1. Experience of regulatory interaction such as authority consultation query response
2. Experience of JNDA submission including CTD preparation
3. Having biopharmaceutical knowledge （e.g. IVIVC） and being familiar with bioanalytical regulations.

歓迎 Nice to have
・ Experience of clinical development of new modalities such as oligonucleotide therapeutics and cell therapeutics
・ Experience of biopharmaceutical modelling （e.g. Gastro+）

■資格 License
必須 Mandatory
・ Master degree （speciality: clinical pharmacology pharmacokinetics or pharmacometrics）

歓迎 Nice to have
PhD （speciality: clinical pharmacology pharmacokinetics or pharmacometrics）

■能力 Skill set
必須 Mandatory
1. Well known the requirements in ADME and clinical pharmacology areas
2. Well versed in Japan guidelines related to CP PK and ADME

[Only for pharmacometrician]
Programing skills such as NONMEM R Python etc.

歓迎 Nice to have
・ Have a good knowledge about new modalities

■語学 Languages
必須 Mandatory
日本語 Japanese：
・ Read/write scientific documents including data speculation in English/Japanese
・ Communicate and discuss CP/DMPK topics with the key stakeholders and experts in English/Japanese practically
・ Make a Japanese presentation

歓迎 Nice to have
英語 English：
・ Read/write scientific documents including data speculation in English/Japanese
・ Communicate and discuss CP/DMPK topics with the key stakeholders and experts in English/Japanese practically
・ Make a English presentation

Company Description

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