CareerCross

【800～1500万円】Immunology Japan Program Clinical Head

臨床開発リーダー・臨床開発プロジェクトマネージャーのご経験のある方は歓迎です。

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
非公開

Job ID
1487994

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
8 million yen ~ 15 million yen

Work Hours
09:00 ～ 17:45

Holidays
【有給休暇】初年度 20日 1か月目から 【休日】完全週休二日制 土・日・祝日、ゴールデンウィーク（4/29 5/5）、夏季・…

Refreshed
August 1st, 2024 15:11

General Requirements

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

【求人No NJB2192968】
■Job Purpose:
The Japan Program Clinical Head （JPCH） is responsible for clinical program activities for approval and post approval commitment for Re examination in Japan. The JPCH is responsible for one or more clinical programs across indications involving one or multiple compounds. The JPCH closely works with Japan Project Head （JPH） as well as Global Program Clinical Head （GPCH） and inputs the risk benefit assessment for the program（s） and as the member of Global Clinical

Team（s） （GCT） provides the inputs regarding the design implementation and execution of a clinical development program（s） including post approval commitment to support decision milestones regulatory requirements and market access from Japan point of view. The JPCH may contribute to disease area strategy.

■Major Activities:
1） Is an extended member of the GCT as representative of Clinical Development Japan （CD J）
2） Is a member of JPT and drive the clinical development in Japan
3） May serve as the CD J Representative on NIBR clinical/project teams in Japan （EAGLE: Early AGile LEadership Team in pharma） JPT: Japan program team in oncology） to drive transition of pre FIH （First In Human） projects to Transition Decision Point （TDP） for clinical development strategy in Japan
4） Play medical lead role in Japan initiated studies in collaboration with GPCH/CDMD
5） May support Business Development Licensing （BD L） activities for Japan clinical assessment
6） Post TDP lead the development and execution of Japan clinical strategy. Provides Japan inputs to GPCH for developing an endorsed Clinical Development Plan （CDP） in line with the Target Product Profile （TPP） which is designed for successful regulatory approval/market access for one or multiple treatment indications and/or multiple programs in Japan
7） Is responsible for Japan input to the creation of clinical components of key documents （e.g. Clinical Trial Protocols （CTPs） Investigator's Brochures Clinical Study Reports （CSRs） regulatory documents including maintenance of product licenses registration dossiers Re examination application dossier value dossiers pharmacoeconomic dossiers） with high quality and consistency with CDP and TPP. Support registration market access commercialization and maintenance of product licenses （e.g. Core Data Sheet Periodic Safety Update Report J RMP clinical benefit
risk assessment for license renewals） for the compound（s） 8） Together with Patient Safety provide GPCH with Japan input regarding continuous evaluation of drug safety profile including safety monitoring of clinical studies and signal detection from post marketing surveillance （PMS）
9） As the medical/scientific expert contribute interactions with Japan external stakeholders （e.g. regulatory authorities key opinion leaders data monitoring committees advisory boards patient advocacy groups） Japan internal stakeholders （e.g. JPT GCO/Study Site Operations Research Translational Medicine Medical Affairs Marketing Pharmacovigilance （PV） Health Economics Outcomes Research etc.） and internal decision boards lead clinical related health authority （HA） activities including development of briefing book and answers for questions from HA
10） Lead discussion for post approval commitment strategy in JPT and Japan submission team （JST） and contribute to Team for Re examination excellence （TREE） for PMS and Re examination activities including the review of Re examination dossier.
11） Support JCDH with leading the peer review of CDPs CTPs and other clinical documents across various indications and programs; and with driving excellence across clinical trial strategy design and execution as a delegator of regional reviewer
12） Contribute to development of TA strategies
13） Support Japan publication and clinical communication strategy in coordination with MA Japan and Medical Writing and provides input into key external presentations
14） Drive scenario development for Clinical Development to support decision analysis and optimal resource allocation in Japan program（s）
15） Responsible for medical/scientific training of relevant Japan stakeholders on the disease area and compound/molecule. May serve as speaker for medical/scientific training in Japan
16） Lead or serve on Japan process improvement work streams act as Subject Matter Experts for standard operating procedures or trainings and/or contribute to other cross functional or Clinical Development line function initiatives
17） Provide on boarding coaching and/or mentoring support; develop and foster Clinical Development culture
18） Ensure adequate reporting of adverse events / technical complaints / compliance issues in accordance with company procedures
19） 100% timely delivery of all training requirements including compliance
20） May serve as JCDM concurrently depending on project size or resource allocation

Required Skills

■Education:
・ Advanced degree in life sciences/healthcare （or clinically relevant degree: MD or equivalent PhD PharmD degree is preferable） required.
Specialization in a subspecialty may be needed. Advanced clinical training/knowledge in medical/ scientific area aligned with TA required.

■Experience/Professional requirement:
・ ・5 years of involvement in clinical research or drug development in an industry environment spanning clinical activities in Phases I through III/IV including submission dossiers （In case MD holder equivalent medical experience is needed）
・ Advanced knowledge of assigned therapeutic area required with the capability to innovate in clinical development study designs that provide relevant evidence to decision makers and to interpret discuss and present clinical trial or section program level data
・ Thorough knowledge of GCP and GPSP clinical trial design statistics and regulatory/clinical development process
・ Experience with submissions and health authorities required
・ Demonstrated ability to establish strong scientific partnership with key stakeholders
・ Demonstrated leadership and team management skills with a documented track record of delivering high quality projects/submissions/trials in pharmaceutical or biotech industry
・ Considerable organizational awareness including extensive experience working cross functionally and in clinical teams
・ Excellent management interpersonal communication （both written and oral） and problem solving skills
・ Excellent negotiation and diplomatic skills

■English Skill:
・ Fluent oral and written English

Company Description

ご紹介時にご案内いたします