CareerCross

【800～1500万円】Japan Program Clinical Head （IMM）

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。

募集職種

人材紹介会社
株式会社ジェイ エイ シー リクルートメント

採用企業名
非公開

求人ID
1493992

業種
医薬品

会社の種類
外資系企業

雇用形態
正社員

勤務地
東京都 23区

給与
800万円 ~ 1500万円

勤務時間
09:00 ～ 17:45

休日・休暇
【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・…

更新日
2024年10月10日 19:00

応募必要条件

キャリアレベル
中途経験者レベル

英語レベル
ビジネス会話レベル

日本語レベル
ネイティブ

最終学歴
大学卒： 学士号

現在のビザ
日本での就労許可が必要です

募集要項

【求人No NJB2192968】
【Job Description Summary】
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.

■Job Description
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．Play medical lead role in Japan initiated studies in collaboration with GPCH/CDMD
４．Post DDP 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
５．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）
６．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 GDO/Trial management 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
７．Contribute to development of TA strategies （Rheumatology area）
８． Provide on boarding coaching and/or mentoring support; develop and foster Clinical Development culture
９． Ensure adequate reporting of adverse events / technical complaints / compliance issues in accordance with company procedures
１０． 100% timely delivery of all training requirements including compliance

■Key Performance Indicators
The indicators below are applied for clinical related activities in Japan
Excellence in establishing clinical development and Re examination strategy across various indications and programs with alignment across functions
Apply effective clinical research methodology including trial design/analyses efficacy endpoints safety assessments and risk management across disease area
Robust evidence of quality medical/clinical review of trial data development of CSRs
Support TA through high quality contributions to CDP and protocol reviews
Timely development of quality disease/program clinical standards publications and internal/external presentations
Timely delivery and submission of high quality clinical program data in a cost effective manner
External acceptance of clinical data and risk benefit assessments by key decision makers including Health Authorities pricing and reimbursement bodies
Well contributed effective and engaged GCT（s） and GPT （as needed）
Clearly demonstrate Novartis Values and Behaviors

スキル・資格

■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 （Rheumatology 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/or 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 （or intermediate） oral and written English

会社説明

ご紹介時にご案内いたします