

【800 ~ 1400万円】Senior Manager Senior Japan Clinical Lead

ブリストル・マイヤーズ スクイブ株式会社での募集です。 臨床開発リーダー・臨床...

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
ブリストル・マイヤーズ スクイブ株式会社

求人ID
1619907

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 ~ 1400万円

勤務時間
09:00 ~ 17:15

休日・休暇
【有給休暇】初年度:試用期間終了後1 ~ 10日（入社時期により異なる）/2年度目:13日 ※入社後、年間休日日数は年毎に変更がご...

更新日
2026年11月12日 17:00

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
ネイティブレベル

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 NJB2405359】
◆Position Summary / Objective
The Japan Clinical Lead （JCL） serves as the clinical point of accountability for the Japan Development Team and is responsible for the overall Japan clinical development plan for asset（s） in one or more indication（s）. JCL ensures studies are aligned with target la bel indications and designed to meet regulatory quality medical and access goals to fit Japan specific requirement/situation. JCL is responsible for implementation planning and execution of assigned clinical trial

activities and leads communication with the external stakeholders（e.g. TLs PI）to efficiently promote responsible clinical program. Accountable for the scientific data evaluation interpretation and documentation for assigned project development program. For Japan local study fulfills the CS role defined in Global SOP.

◆Position Responsibilities
Accountable for the clinical contribution to the development of each indication strategy including registrational and non registrational studies with the support of the CTPs within the asset and/or indication
Accountable for the design execution and analyses of each study
Accountable for clinical content for CSRs and regulatory documents（e.g. briefing books submission documents and regulatory responses）
Champions a quality focused mindset and ensures adherence to GCP and compliance obligations for clinical conduct
Represents Clinical Development in both internal and external forums as the consulted authority for the disease area including within Business Development function
Provides clinical leadership and disease area expertise into integrated disease area strategies
Collaborate and serve as primary liaison between external partners for scientific advice
Serves as Primary Clinical Representative in Regulatory interactions
Sets executional priorities and partners with CTP and operation team to support executional delivery of studies
Accountable for top line data with support of CTP and Statisticians
Maintain a thorough understanding of assigned protocols and protocol requirements; educate supporting team members
Evaluate innovative trial designs（collaboration with Japan CTP）・ Ensure global clinical study protocol is applicable to local medical practice（manage local protocol amendment if needed）
Proactively identifies potential study level risks and drives the execution of mitigation strategies
Serve as CS in Japan local studies

o Responsible for implementation planning and execution of assigned clinical trial activities
o Successfully leads plans and executes trial level activities for multiple trials with minimal to moderate level of supervision
o Co Leads study team meetings in partnership with Global Trial Manager; and collaborate with cross functional study team members
o Plan and lead the implementation all study startup/conduct/close out activities as applicable（collaboration with GTM）
o Protocol and ICF development process; including writing reviewing adjudication/resolution of cross functional comments and ensuring high clinical quality（collaboration with Scientific Writing）
o Site facing activities such as training and serving as primary contact for clinical questions
o Activities related to data generation and validation including CRF design clinical data review/query resolution; ensure consistent quality data review（collaboration with DM）
o Clinical data trend identification; provide trends and escalate questions to Japan CTP
o Develop clinical narrative plan; review clinical narratives
o Provision of information required by Global Trial Manager for development of trial budget CRO scope of work etc.
o Review development of site and CRA training materials and presentation at SIV and Investigator meetings and support on Study committee（e.g. DMC）activities

Demonstrate leadership as an active member of cross functional teams task forces or local and global initiatives
Effectively influence team and collaborate with senior stakeholders address complex problems and challenges with positive outlook able to deliver results with high level professionalism
Coach the CL in the Clinical Lead work for development of products in Japan from study planning to JNDA filing and thereafter

スキル・資格

◆Degree Requirements
A minimum of 5 years of clinical development / industry experience preferred
Expertise in the design analysis publication and execution of multiple clinical trials（e.g. significant experience as a senior clinical leader）.
Adequate knowledge of pharmaceutical development process.
Strong experience in clinical science clinical research or equivalent.
Experience in a matrix team composed of multiple functional organizations.

◆Experience Requirements
Ability to deliver the outcomes under the ambiguity or complexity
Ability to partner with people at all levels of the organization
Ability for proactive proposal building and proactive action takings without detailed instructions
Ability to respond flexibly to the changing project/task priorities and work assignments.
Ability to influence and negotiate without specific authority.
Ability to take a risk and to manage it without jeopardizing quality and/or compliance
Proficient knowledge and skills to support program specific data review trend identification data interpretation
Proficient knowledge of GCP/ICH drug development process study design statistics clinical operations
Able to synthesize internal and external data to produce a clinical strategy
Able to ensure that the clinical program will result in a viable registrational strategy
Able to work with other stakeholders to ensure a robust enterprise level strategy for asset（s）and indication（s）including early late and post marketing development in Japan
Fluent in spoken and written English for business is preferred

会社説明

医薬品の輸入、製造、販売