CareerCross

【900～1400万円】【R D】Japan Clinical Operation Program Development L…

アストラゼネカ株式会社での募集です。 臨床開発リーダー・臨床開発プロジェクトマ…

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
アストラゼネカ株式会社

求人ID
1487892

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
900万円 ~ 1400万円

勤務時間
09:00 ～ 17:15

休日・休暇
【有給休暇】有給休暇は入社時から付与されます 【有給休暇】 初年度 4～16 日 （ 1 か月目～ ） 入社月により付与日数が…

更新日
2024年08月01日 15:09

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 NJB2218319】
■職務内容 / Job Description
Lead Japan Clinical Operation Program （JPD Lead） is accountable/responsible for leading the project planning for clinical operation in Japan R D. The span of activities is broad covering clinical activities in both early and late drug development registration/submission and post registration product maintenance phases and will include local and global working.
The JPD Lead is responsible for planning oversight on related studies and mediator among Japan study team project team

and Global project/clinical team.
The JPD Lead is one of the key members of Japan project team to represent Clinical Operation arena and to contribute JPT deliverables.

■Key Responsibilities
1. Project Level
・Contribute to planning and execution of Japan clinical operational part in Japan development plan with high quality insights from clinical operation arenas until ID approval and responsible for leading a cross functional team of clinical experts in the planning and delivery of a defined clinical studies to quality budget time managing resource and risk
・Lead strategies for the site selection/patient recruitment in feasibility assessment through external key stakeholders involvement to optimize the project deliverables
・Responsible for project management including the development baselining and maintenance of realistic up to date and appropriate quality project and study plans in agreed study planning systems
・PMDA interaction; Contribute to operational strategic interaction with PMDA
・JNDA; Responsible for health authority GCP inspection management
・Key Investigators Management/Engagement ; Act as a key point of contact for clinical operations related relationship with Key investigators and National Lead Investigators
・PUBLICATION; Contribute to author selection by providing required information and act a key point of contact for author/KEE

2. Study Level
・Lead program operational feasibility assessment including project management of the scope schedule and budget
・Provide operational input into study feasibility study specifications and vendor/partner contracts
・Handover study specification including the strategic context and the PMDA’s feedback of the clinical study discussed at Japan project team to study team
・Lead a large/complex work situation or oversight a clinical study and the process to identify and solve operational issues and drive delivery to plan through internal stakeholders or external partners engagements
・Act as a point of contact with external partners for externally managed/outsourced studies as needed
・Oversight of the study delivery through regular communications with Global counterpart and relevant persons in Japan study/site management functions to anticipate study requirements and mitigate risks

3. Collaboration with Marketing Company
For study support act as a point of contact to MSL in Medical Affairs to collaborate on e.g. Programme feasibility/KEE Engagement developing site candidates list information exchange on sites
4. Others
Task outside projects; May be assigned responsibility for leadership and program/project management of non drug project work as the representative of Japan for the global initiatives developing new processes in Japan R D or the industry activities

スキル・資格

■応募資格（経験、資格等）/ Qualification （Experience Skill etc.）

【経験 / Experience】

＜必須 / Mandatory＞

・At least 5 years’ experience in pharmaceutical industries or multinational healthcare organization.
・Extensive knowledge of clinical operations project management tools and processes
・Proven experience of clinical development / drug development process in various phases of development and therapy areas.
・Proven ability to learn by working in multiple phases TAs and/or different development situations.
・Experience from leading clinical projects and deliverables or similar expertise from other areas of drug development （such as pharmaceutical development）.

＜歓迎 / Nice to have＞

・Working with external bodies such as co development companies and key opinion leaders as a leading person.
・Leadership of significant cross functional change programmes/initiatives

【Education】

＜必須 / Mandatory＞

・Bachelor’s Degree in Science or related discipline.

【能力 / Skill set】

＜必須 / Mandatory＞

・Consistently exhibits;

Drives Accountability focuses on delivery/results; meets or exceeds expectations

Works Collaboratively effective in leading and being a member of teams both locally and internationally
・Creative and Innovative: Seeks to improve continuously where it counts based on good awareness of external competitive practice and creativity and initiative.
・Ethics maintains high standards including a commitment to AstraZeneca values policies and employment principles
・Cultural Awareness: Is aware of and sensitive to cultural differences and their impact on communication expectations and performance.
・Business English （Achieve common understanding at the context level with customers）

会社説明

医療用医薬品の開発、製造及び販売