CareerCross

【900～1400万円】【R D】Associate Director Site Management Monitorin…

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...

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
アストラゼネカ株式会社

Job ID
1497893

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
9 million yen ~ 14 million yen

Work Hours
09:00 ～ 17:15

Holidays
【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…

Refreshed
November 21st, 2024 17:00

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 NJB2254605】
【R D】Associate Director Site Management Monitoring （ADSMM） R D Development Operations Late Development Oncology Clinical Operation 1

■職務内容 / Job Description
Ensure study deliveries with appropriate quality in terms of site management and monitoring part.

Responsible for developing staff（Senior Clinical Research Associate and Clinical Research Associate） capabilities to achieve high level of performance and productivity with the potential to lead and deliver studies in Japan.

・ Ensure study deliveries within agreed timelines cost/resources and appropriate quality in terms of site management monitoring perspectives
・ Contribute to continuous improvement activities including study processes and other procedures
・ Ensure effective clinical and operational feasibility assessments of sites level to execute study deliveries
・ Ensure quality of selection of investigators sites and SMOs （if needed）
・ Ensure subject recruitment strategy including risk management of site management and monitoring areas is performed for every clinical trial and contingency plans are in place
・ Ensure necessary actions are taken as a result of audits and regulatory inspections
・ Ensure contribution for regulatory inspections of site management monitoring areas
・ Ensure the sharing of experiences and best/bad practices in activities related to managing sites and delivery of clinical trials from site management and monitoring perspective
・ As a member of the Development Operations Leadership Team to contribute to the effective execution and implementation of the Japan Development Operations and R D strategy
・ Demonstrate accountability on the quality of deliverables from job holder’s function by confirming the process and communicating with their staffs regularly and proactively to identify the issues and potential risks that may jeopardize the quality of the deliverables and take necessary actions （e.g. review the contents training of the staffs and solving process issues etc.） in timely manner
・ Develop staff within the group to lead and deliver reliable cost effective and high quality clinical trial data optimising processes from operational site level study feasibilities through to study closures
・ Conduct Performance and Talent Management （in line with HR plans） in order to attract develop and retain the best personnel （talent base）
・ Compliance with AZ Procedural Documents international and local guidelines such as ICH/GCP and J GCP
・ Perform regular co monitoring/accompanied site visits in order to ensure staff skills and knowledge
・ Model behaviours that foster AstraZeneca’s preferred work environment including adherence to AZ Code of Conduct
・ Plan and manage workload of staffs ensuring appropriate supply of resources including use of contract staffs
・ FTE capacity planning and monitor and control workload of staffs in the group in accordance with appropriate SHE and Compliance standard

Required Skills

■応募資格（経験、資格等）/ Qualification （Experience Skill etc.）
【経験 / Experience】
＜必須 / Mandatory＞
・ Experience in working within clinical development
・ Experience in overall clinical development including monitoring activities study leadership and project management
・ Capability to engage in discussions with internal and external stakeholders on scientific and practical aspects of the Study Design Concept/Clinical Study Protocol
・ Basic knowledge and experience of quality management
・ Experience in training and development

＜歓迎 / Nice to have＞
Working with external bodies such as co development companies and key opinion leaders as a leading person.

【資格 / License】
＜必須 / Mandatory＞
・ University degree （or equivalent） preferably in biological sciences or discipline associated with clinical research

【能力 / Skill set】

＜必須 / Mandatory＞
・ Effective in leading motivating and empowering others in order to accomplish individual and team objectives
・ Good working knowledge of ICH GCP/AZ SOPs and Japan PMDA regulations
・ Effective language （Japan English） skills
・ Communication skills
・ Presentation skills
・ Coaching skills
・ Problem solving skills
・ Project management skills
・ Fiscal and financial awareness
・ Consistently exhibits at target level 2 for AZ Leadership capability（Drives Performance Develops People and Organization Works Collaboratively）

Company Description

医療用医薬品の開発、製造及び販売