【1130～1550万円】【AstraZeneca】【R D】Associate Director Clinical Qua…

アストラゼネカ株式会社での募集です。 臨床開発QC・GCP監査のご経験のある方…

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
1578522

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
1100万円 ~ 1500万円

勤務時間
09:00 ～ 17:15

休日・休暇
【有給休暇】入社7ヶ月目には最低10日以上 【有給休暇】※入社月により付与日数が異なります。詳細はオファー時に通知いたします …

更新日
2026年04月30日 02:00

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 NJB2360460】
■職務内容 / Job Description
Associate Director Clinical Quality Management （ADCQM） leads the planning and implementation of all quality activities adapting to changes in the environment through relevant Clinical Quality Management System. ADCQM is individual contributor and skill expert which meets organizational needs and professional role model for CQM. ADCQM is responsible for proactive contribution to Japan Development Operations（J DO） and global member in Quality Management or Quality

Assurance to develop capabilities to・achieve high level of performance and productivity in Japan/global.

ADCQ is responsible for

・ Contribute to the effective execution and implementation of the CQM J DO and R D strategy.
・ Lead the planning and implementation of all quality activities in J DO through relevant Clinical Quality Management System.
・ Drive the robust communications/networking with AZ global members to ensure our processes are aligned and that we are consistently applying processes and adapting to changes in the environmentin the document quality areas.
・ Ensure Always Inspection Ready（AIR） including PMDA EMA FDA and other Health Authority inspection ready in Japan:o Guides study teams to adopt clinical study audit and inspection ready standardo Collaborates with DOLT to ensure the all Clinical Studies delivered by J DO are inspection ready and supports J DO related audits and inspections
・ Lead to analyses and identifies improvement opportunities by collecting quality related data / quality issue （QI） and communicating with Process Owners（PO） System Owners Subject Matter Experts and DOLT.
・ Lead to assist study teams during development and implementation of CAPA plans and investigations.
・ Provide a robust quality risk and issue management expertise to J DO.
・ Provides a compliance risk and issue management service to J DO.
・ Ensure that relevant new regulations are assessed and appropriately encompassed in J DO.
・ Build and maintain strong customer relationships with QA Compliance Manager PO and DOLT etc.
・ Leads keeping simplification and consistency of description in Procedural Document including Local SOP and working instructions working package and training package within DO R D Japan and Global.
・ Model behaviours that foster AstraZeneca’s preferred work environment including adherence to AZ Code of Ethics

スキル・資格

【経験 / Experience】
＜必須 / Mandatory＞
' Leadership of significant cross functional change programmes/initiatives with Proven courageous leadership consistently challenging the status quo and promoting motivation and empowerment of others in order to accomplish individual team and organizational objectives.
At least 5 years’ experience in the pharmaceutical industry including at least 3 years’ experience in Clinical Development / Assurance / Advice
Well informed understanding of drug development process and related GCP activities and understanding of skills and knowledge required for successful delivery of a clinical trial e.g. GCP monitoring data management study drug delivery etc.
Proficient knowledge of local and international regulations and guidelines
Knowledge of Clinical Procedural Documents

＜歓迎 / Nice to have＞
' Process Management including developing / reviewing Procedural Documents in Japanese / English
Professional excellence: Background of high professional achievement and willingness to encourage this in others
Experience in leading or being involved with Business Process Management

【資格 / License】
＜必須 / Mandatory＞
Bachelor’s degree （or equivalent） preferably in biological science or discipline associated with clinical research.

＜歓迎 / Nice to have＞
MBA Project Management Professional（PMP）

【能力 / Skill set】
＜必須 / Mandatory＞
' Leadership
Excellent written and verbal communication skills negotiation collaboration and interpersonal skills in a multicultural environment
Integrity and high ethical standards
Manages change with a positive approach to the challenges of change for self team and the business. Sees change as an opportunity to improve performance and add value to the business.・
Ability to look for and champion more efficient and effective methods/processes of delivering quality clinical trials with reduced budget and in less time.
Makes effective decisions despite uncertainty and/or incomplete information.
Communicates clearly to ensure alignment and empowers others with decision making authority as appropriate.
Seeks diverse views and incorporates them where appropriate in order to develop better proposals and creative solutions for the business.

＜歓迎 / Nice to have＞
Consistently exhibits Leadership capability as below
Commitment to Customers Integrity; Focuses on What’s Important: Balances and prioritizes across diverse and competing customers needs and opportunities.・
Demonstrates the courage to make tough and ethical decisions about where to devote resources.

会社説明

医療用医薬品の開発、製造及び販売