【1100〜1600万円】Seninor Manager Quality Assurance APAC R D Qualit…

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…

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
アストラゼネカ株式会社

Job ID
1573300

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
11 million yen ~ 16 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
January 22nd, 2026 15:06

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 NJB2345038】
As the independent second line assurance function for R D our mission in Quality Assurance is to achieve enduring excellence in auditing quality management quality risk assessment and enhance the R D quality mindset for the benefit of our patients.
The job holder is responsible for:
・ Planning leading conducts and reports audit activities for R D GxP risk based audit programs （GCP GVP GRP Lab GCP

GLP）
・ Support of GxP inspection activities
・ Management of CAPAs related to audit and/or inspection findings in collaboration with QA colleagues and functions owning the issues.
・ Supporting the management of business relationships with defined stakeholder groups for quality strategic development and quality management activities for these stakeholders.

■Audit
・ Plans leads conducts and reports audits in assigned GxP areas （GCP GVP GRP Lab GCP GLP） such as investigator site and/or project audits
・ Supports lead auditors in the planning conduct and reporting of more complex audits such as Process / System External supplier
・ Works with contract personnel or consultants to prepare conduct and report outsourced audits

■Inspection
・ Supports Quality Assurance team members to manage and prepare for regulatory inspections

■CAPA
・ Assesses need for and assists in development of CAPA plans approves and monitors plans to completion for assigned audits
・ Assists with the continuing follow up of agreed audit CAPA actions from across QA to assist in the monitoring of QA Key Performance Indicators

■General Accountabilities
・ Ensures own tasks are performed to current practices and in accordance with company policies standards SOPs and guidelines
・ Promotes a culture of ethics integrity and continuous improvement that focuses on delivering efficiencies and planned business benefits
・ Communicates effectively with QA colleagues and business stakeholders
・ Maintains knowledge of relevant industry information affecting quality and compliance arena
・ May provide responsive and proactive quality and compliance advice to defined customers.
・ Support quality and compliance risk management for functional area using risk framework standards to define risk and develop mitigation recommendations
・ Travel expected

Required Skills

■Essential
・ Degree level education or equivalent experience in clinical development and quality management
・ Experience in pharmaceuticals or a related industry
・ Excellent analytical written and oral communications skills
・ Fluent in written and spoken English
・ High ethical standards trustworthy operating with absolute discretion
・ Collaborative influencing and interpersonal skills ・ curious to understand business environment
・ Skilled at managing using technology
・ Ability to develop professional networks with stakeholders

■Desirable
・ Audit Experience
・ Supplier qualification
・ Experience of regulatory health authority GxP Inspections

Company Description

医療用医薬品の開発、製造及び販売