【1100〜1600万円】Associate Director Quality Assurance APAC R D 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…

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
アストラゼネカ株式会社

Job ID
1573299

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 NJB2345040】
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 Associate Director Quality Assurance is responsible for:
・ Planning leading conducting and reporting audit activities for R D GxP risk based audit programs （GCP GVP GRP Lab

GCP GLP）
・ Delivery of proactive GxP inspection support and management
・ Management of significant CAPAs related to audit and/or inspection findings in collaboration with functions owning the issues.
・ Managing business relationships with defined stakeholder groups for the quality management activities （quality risk issues process etc.）.

■Audit
・ Plans leads conducts and reports audits in assigned GxP areas and types e.g. investigator site audit system or process audits and vendor audits.
・ Participate in and may lead directed （For Cause） audits.
・ Works with contract personnel or consultants to prepare conduct and report outsourced audits
・ Leads Supplier qualification activities （SQA） as assigned
・ Identify and assess gaps during supplier qualification assessments
・ Supports Due Diligence activities as assigned

■CAPA
・ Assesses need for and assists in development of CAPA plans approves and monitors plans to completion
Inspection
・ Provides QA oversight and/or management of regulatory GxP inspections
・ Collaborates with Quality Assurance lead to manage and prepare for regulatory inspections as assigned including providing training to the organisation as needed.

■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
・ Leads training for colleagues and business stakeholders as required.
・ Involved in and may lead the development and/or revision of QA processes projects and tools
・ Mentors QA colleagues
・ Provides general support related to regulatory authority inspections as and when required
・ Provides responsive and proactive quality and compliance advice to defined customers effectively influence assigned area by being relevant GxP/quality system expert
・ 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 or 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
・ Strong collaborative influencing and interpersonal
・ skills ・ curious to understand business environment
・ Skilled at managing using technology
・ Ability to maintain and create professional networks with stakeholders
・ Supplier qualification

■Desirable
・ Project management experience
・ Experience in managing regulatory health authority GxP Inspections
・ Key Account management
・ Audit expertise

Company Description

医療用医薬品の開発、製造及び販売