



# グローバル企業・<mark>外資×ハイクラス転職</mark> 「語学力」を活かす転職なら、JAC Recruitment

# 【1000~1500万円】 【External Quality】 Associate Quality Director

アストラゼネカ株式会社での募集です。 メディカルGQP・GMP・品質保証・品質...

#### Job Information

#### Recruiter

JAC Recruitment Co., Ltd.

#### **Hiring Company**

アストラゼネカ株式会社

#### Job ID

1524907

#### Industry

Pharmaceutical

#### **Company Type**

International Company

#### Job Type

Permanent Full-time

#### Location

Tokyo - 23 Wards

#### Salary

10 million yen ~ 15 million yen

# **Work Hours**

09:00 ~ 17:15

## Holidays

【有給休暇】【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異なります。詳細はオファー時に通知いた...

## Refreshed

April 3rd, 2025 11:00

# 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 NJB2280811】

The incumbent is responsible for the Quality management of assigned External Suppliers within Procurement Quality AsiaPac teams. They are responsible for all Quality activities that directly support execution of Quality Management of Suppliers for assigned suppliers. This includes but is not limited to the Quality System oversight and/or performance of the following activities: change control product quality complaint S L complaint and deviation investigations quality issue management and escalation Quality Agreements (establishment and maintenance) between AZ and External Suppliers

and between EQ and AZ Operations Sites.

Within the External Quality (EQ) organization the job holder is responsible for the oversight and ownership of Quality System (s) . They will support the Quality Professionals involved in Quality Supplier and Product Supply Chain Management within the assigned categories.

In addition the preparation and submission of periodic Supplier Quality Assessments Regulatory Agency interactions and serving as Quality leaders on NPI new supplier introductions In Licensing strategic sourcing projects process optimization and product transfer projects as these relate to Quality Supplier management are within the scope of this role. Regulatory Agency interaction includes preparation for and management of Regulatory Agency inspections at External Suppliers and AZ sites (when External Suppliers are assessed) .

# Required Skills

## 【経験/Experience】

(歓迎/ Nice to have)

- · Experience working in a PCO/PET organization or Lean/Six Sigma training.
- · Multi site / multi functional experience
- · Proven experience in Quality Assurance or combination of Quality and Technical
- · Masters Degree in Quality Assurance/Regulatory Affairs or other advanced scientific field

#### 【資格 /License】

(必須/Mandatory)

Bachelor degree in a science / technical field such as Pharmacy Biology Chemistry or Engineering (Note: there may be specific additional requirements depending on the regulations in each country). Proven broad experience in either the pharmaceutical operations environment or pharmaceutical Quality Assurance role.

【能力/ Skill set】

(必須/ Mandatory)

- · Strong demonstrated knowledge of cGMPs Quality Systems and the pharmaceutical supply chain environment. Also strong understanding of industry standards such as Pharmacopeia ISO standards etc.
- Excellent oral and written communication skills [English and local language (s) ] pecifically required essentials for Career Level E:
- · Demonstrated experience working cross functionally and managing significant improvement initiatives (e.g. project management skills)
- · Strong problem solving skills
- · Strong negotiating/influencing skills
- · Ability to work independently under his/her own initiative.

#### 【その他/ Others】

(必須/ Mandatory)

· Ability to travel nationally and internationally as required approximately 10% of their time.

#### (歓迎/ Nice to have)

- · PCO members or equivalent team
- · Category/Sub Category Team members
- · Quality and other support groups within or across sites
- · Regulatory Affairs (including GQO CMC RC)
- · GOO
- Global Supply Managers/Directors
- $\cdot$  Pharmaceutical Technology and Development and Pharmaceutical Sciences

# Company Description

医療用医薬品の開発、製造及び販売