



【1000～1500万円】 【Global Supply Team】 Quality Lead (GST QL)

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...**

#### 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

1524904

##### 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

1000万円～1500万円

##### 勤務時間

09:00～17:15

##### 休日・休暇

【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...

##### 更新日

2025年03月06日 16:24

#### 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 NJB2284038】

Typical Accountabilities:

- Provides expert Quality Assurance Technical input on New Product Introduction Asset Strategy and/or Value Delivery projects
- Coordinates change for significant and broad pharmacological changes or Good Manufacturing Practice requirement changes affecting Global External Sourcing supplier

- Accountable for decisions and advises the Process Execution Team regarding quality and pharmaceutical technology issues within the area of expertise
- Maintains a high level of understanding of relevant production processes and quality systems
- Performs Quality Assurance Technical review of current Good Manufacturing Practice documentation
- Collaborates with and influence other Quality professionals across the organization to ensure consistent application and execution of key quality system
- Accountable for providing Quality Assurance Technical support for Process Execution Team related cost saving initiatives value creation performance standards continuous improvements and issue resolutions
- Collaborates with and influence other Process Execution Team /assigned area members to facilitate process improvements and risk assessments; benchmarks internal and external Quality Assurance practices to identify innovative efficient and effective practices

The GST QL is a key role in the Global Supply Team (GST) that provides brand aligned quality leadership across the E2E supply chain throughout the lifecycle of a brand as Supply Chain complexity is increasing.

This position requires strong cross functional ways of working across the supply chain nodes AZ Sites/Roles/Functions (PQL/GSC S/GSM/Corporate Quality etc) .

These individuals will manage multiple Brand Supply Chains (participate in more than one GST) .

The GST QL must possess capability in understanding impact of change mitigating risks and responding to trends in Quality and supply chain principles while embracing Modern Quality Professional (MQP) elements.

This includes but is not limited to the following areas:

**SUPPLY CHAIN DESIGN** · The GST QL is accountable for the Quality evaluation of supply chain design. This includes the development of Quality elements of the Supply Chain mapping licence structure across the Supply Chain and providing Quality Oversight to fulfil the MAH responsibilities.

**QUALITY LEADERSHIP** The GST QL leads a brand quality network to ensure appropriate escalation and collaborative resolution of Quality issues that may impact supply. The GST QL will support Issue Management Teams with a focus on Brand Quality Impact.

**BRAND QUALITY RISK** · The GST QL is responsible to facilitate an E2E Brand Quality Risk review which considers the Quality Performance of both the product (Brand Health) and all nodes across the supply chain and provide any escalations into the GST.

**BRAND CHANGE** · The GST QL will act as the Quality Approver on changes to the Supply Chain design and management working collaboratively with colleagues across the brand network to implement changes and manage associated risks. They will also be responsible with the GST to review the portfolio of changes across the Brand.

**BRAND HEALTH** · The GST QL will review a series of Brand specific Quality Metrics and share this performance with the GST.

**ALLIANCE/CUSTOMER QUALITY MANAGEMENT** · The GST QL will act as the key Quality Contact for the Quality function in the customer organisation (AZ MC 3PS Customer Alliance Partner) ensuring that communication and issue resolution is handled in accordance with an established Quality Assurance Agreement/Quality Framework.

Job Responsibilities (to include key result areas specific accountabilities tasks etc.)

In addition to the general description of the role the following summarize key result areas specific accountabilities and / or tasks etc. associated with this role:

Timely and efficient delivery of all Supply Chain quality aspects for NPI BD and Change projects within their portfolio  
 Accountable for the quality evaluation of SC design and set up whilst maintaining downstream visibility of timings and risk.  
 Quality Evaluation and approval of any non standard supply for the brand (Including routine SAOC One off Sales) .  
 Responsible for Creation and Maintenance of Quality flow for Supply Chain Maps and associated master data.  
 Develops and maintains effective business relationships with Customers or Partners.  
 Accountable for Supply Chain QA decision making (Design Licence to Operate Change Risk Flow) ; works directly with the GSSD/GBP the Brand Quality Network and other GST team members to deliver objectives.  
 Support Business Development activities via Due Diligence and Deal Processes.  
 Acquire process and product knowledge for products supported.  
 Support the GST in the resolution of complex supply issues from a Quality perspective. Take the lead in escalated Quality issues. Support the delivery of optimized solutions and influence key stakeholders and decision makers across the network.  
 Provide Coaching and Mentoring on Quality Items to aligned Brand teams.  
 Work with Quality stakeholders via the Brand Quality Network to implement GST strategies and escalate Quality constraints/Risks.  
 Leads Quality and Compliance with internal QCMs and external Regulatory requirements across the supply chain.  
 Supports the creation and maintenance of Quality SOPs and QCMs.  
 Stays abreast of evolving regulatory compliance practices and recommends implementation strategies to Global Supply Team.  
 Responsible for Brand Quality Risk management and mitigation strategies.  
 Collaborates and influences across the Brand Supply Chain team to facilitate process improvements with a focus on improving Quality.  
 Responsible for reporting and trending Brand Quality metrics and KPIs.  
 Drive a LEAN culture through active participation in Continuous Improvement/Practical Problem Solving Product Supply Chain Strategy Plan Business Continuity Planning and Value Stream Mapping.  
 Model Modern Quality Professional behaviours with all Global Supply Chain activities.  
 Typical Accountabilities (per AZ framework and regulatory expectations) :

Conduct activities and interactions consistent with Company values and in compliance with the Code of Ethics and

supporting Policies and Standards relevant to your role. Report potential issues of non compliance.  
Responsible for all Quality related deliverables to the GST.  
Holistic understanding of supply chain design and management.  
Manage conflict and confidently stand alone on issues when necessary.  
Propose tactical data driven solutions to high level strategic initiatives and complex product issues.  
Support across the Brand Quality Network to drive teams towards identification of true root cause and appropriate CAPA/risk management.

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## スキル・資格

Key Relationships to reach solutions  
Internal (to AZ or team)  
QA and other support groups within or  
across sites  
Operations Quality  
Supplier Quality  
GSC S; GST / GOLT teams  
AZ Sites  
Regulatory Affairs (CMC RC)  
Process Development and Operations functions (PharmSci PT D BPD GTO ESM AZ Sites Device Quality PQL'S)  
External (to AZ)

Global Health Authorities  
Industry bodies and consortiums  
Partners suppliers CMO

### 【Experience】

Mandatory: Degree education. Quality experience (more than 5years)  
Nice to have: Supply Chain experience

### 【Skillset】

Mandatory: Leadership influencing communicator able to work collaboratively.

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## 会社説明

医療用医薬品の開発、製造及び販売