



【1500～1800万円】Associate Director GxP Quality Assurance Japan QA

メディカルGQP・GMP・品質保証・品質管理のご経験のある方は歓迎です。

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

非公開

求人ID

1617258

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

1500万円～1800万円

勤務時間

09:00～17:00

休日・休暇

詳細は求人ご紹介時にご案内いたします。

更新日

2026年10月15日 17:46

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 NJB2416929】

【The Opportunity】

Position Summary

The Associate Director GxP Quality Assurance plays a critical leadership role in supporting the establishment and maturation of the Japan Quality Assurance organization.

Partnering closely with the Head of Quality Assurance this position leads the implementation and execution of Quality Systems Quality Governance processes and GxP Quality Assurance programs required to support a growing Japan

Marketing Authorization Holder (MAH) organization. The role provides strategic and operational quality leadership across product launch activities commercial operations contractor oversight quality event management quality risk management and regulatory inspection readiness.

As the Deputy of Quality Assurance Manager (QAM) the Associate Director plays a key role in supporting decision making for quality related matters and provides independent quality oversight to ensure product quality patient safety supply continuity and compliance with applicable regulatory requirements throughout the product lifecycle.

Key Responsibilities

Quality System Development and Quality Governance

- Establish and maintain the Quality Management System for the Japan MAH organization.
- Lead Quality Governance activities and provide strategic direction for Quality Systems and Quality Compliance programs.
- Serve as the Deputy of QAM and maintain appropriate backup and support mechanisms for critical QA responsibilities.
- Drive continuous improvement of quality processes procedures and compliance programs.

Product Launch Readiness

- Lead Quality Assurance activities supporting product launch and commercialization in Japan.
- Ensure effective implementation and integration of Japan specific regulatory requirements into the Global Quality System throughout the product lifecycle.

External Partner Management

- Conduct quality audits of external partners.
- Establish negotiate and manage Quality Technical Agreements (QTAs) with Contract Manufacturing Organizations (CMOs) logistics providers warehouses call centers and other GxP service providers.
- Provide Quality oversight of outsourced activities and monitor compliance with applicable regulatory and company requirements.

Market Release and Product Quality Oversight

- Oversee CMO activities and Review and/or approve records supporting product release activities.
- Perform final quality review of significant quality events and provide independent quality assessments to support product disposition and release decisions.

Quality Event Management

- Provide Quality oversight for Deviations Change Controls CAPAs Product Quality Complaints Quality Information and other quality events.
- Review quality risk assessments investigation outcomes and proposed corrective actions.
- Conduct quality reviews to support final quality decisions on significant quality issues.
- Ensure appropriate cross functional collaboration and escalation when required.

Quality Metrics and Management Review

- Review quality trend analyses Annual Product Reviews (APRs) and Management Review outputs.
- Lead escalation of significant quality risks that may impact product quality patient safety regulatory compliance or supply continuity.
- Monitor Quality System effectiveness through established quality metrics and performance indicators.

Regulatory Inspection Management

- Coordinate inspection readiness activities across Quality Assurance and other business functions.
- Lead inspection preparation inspection strategy development and inspection management activities.
- Serve as a key Quality representative during regulatory inspections and audits.

スキル・資格

【必須要件】

- 理系分野（薬学、化学、生物学、工学、理学、バイオテクノロジー等）における学士号以上
- 製薬業界における品質保証業務経験5年以上
- GQP、GMP、GDP及び関連法規制に関する知識及び経験
- 規制当局監査・査察への対応経験
- 外部委託先（製造委託先、保管・輸送業者、コールセンター等）との品質関連業務経験
- 市場出荷判定、逸脱、CAPA、変更管理、品質情報等に関する実務経験
- 問題解決能力及び意思決定能力
- グローバルかつクロスファンクショナルな環境でのリーダーシップ経験
- ビジネスレベルの英語力及びネイティブレベルの日本語

【歓迎要件】

- 品質保証責任者又は品質保証副責任者としての経験
- MAHにおける品質保証体制の構築・運営経験
- MAHにおける 製品上市準備及び上市後品質保証活動の経験
- 品質システム、ガバナンス体制の立ち上げ経験
- 規制当局監査・査察をリードした経験
- 委託製造管理及び品質契約締結・管理の経験
- 安全性部門又は薬事部門との業務経験
- CMC関連業務経験（原薬プロセス開発、製剤開発、分析法開発、CMC薬事等

会社説明

ご紹介時にご案内いたします