【1000～1600万円】Assoc. Dir Quality Assurance

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。

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
非公開

Job ID
1575886

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
10 million yen ~ 16 million yen

Work Hours
09:00 ～ 17:30

Holidays
【有給休暇】有給休暇は入社時から付与されます 初年度 12日 【休日】完全週休二日制 ※初年度の有給休暇日数は12日をベースに…

Refreshed
February 5th, 2026 16:06

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 NJB2354379】
We aspire to be the premier research intensive biopharmaceutical company. At our company we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We use the power of leading edge science to save and improve lives around the world. Join our team as an Associate Director Supplier Quality Assurance （SQA） and play a pivotal role in ensuring the integrity and safety of our products through strategic oversight of global API suppliers.

【Responsibilities】
・Serve as the primary Quality liaison for strategic API suppliers ensuring sustained compliance with GMP company standards global regulations （EU FDA others） Annex 1 where applicable and the our company Quality Manual.
・Maintain and negotiate Quality Agreements; ensure alignment with Commercial Agreements and update as needed.
・Assess supplier capability using risk based tools; plan and lead on site/remote audits issue evidence based reports and drive effective CAPA with verification of effectiveness.
・Strengthen supplier Quality Management Systems （change control deviations CAPA OOS/OOT document control training internal audits management review）.
・Review approve and manage supplier change controls; coordinate regulatory impact assessments with cross functional partners.
・Lead investigations into deviations OOS/OOT microbiological excursions stability issues and complaints; ensure robust root cause analysis remediation and required regulatory reporting.
・Provide oversight for technology transfers and support process validation to ensure compliant robust product realization.
・Drive inspection readiness and represent our company during regulatory interactions and inspections.
・Monitor supplier performance via KPIs and periodic reviews; identify trends and implement systemic corrective/preventive actions.
・Collaborate with Technical Regulatory Procurement/Supply Chain and manufacturing sites to ensure alignment timely issue resolution and risk management.
・Proactively escalate critical quality or supply continuity risks to senior management with clear actionable recommendations.
・Coach and mentor supplier and internal teams to build capability and foster a strong quality culture.
・Operate effectively in a global virtual matrixed environment; travel to supplier sites as required and keep the Director SQA informed of status opportunities and issues.

Required Skills

【Required】
・Education: Bachelor’s degree in Chemistry Pharmacy Biology Microbiology Chemical Engineering or a related scientific/engineering field.
・Experience: 8+ years in GMP regulated environments （API and/or drug product） with proven responsibility in Quality Assurance/Quality Control and manufacturing/technical operations.
・Regulatory/GMP expertise: Strong working knowledge of EU FDA and relevant global regulations; familiar with ICH guidelines and Annex 1 （where applicable）.
・Quality Systems: Hands on experience with QMS elements （change control deviations CAPA OOS/OOT investigations document control training internal audits management review）.
・Technical investigations: Ability to lead root・cause analysis and remediation for deviations OOS/OOT microbiological excursions stability issues and complaints.
・Communication: Fluency in Japanese and strong proficiency in English; able to communicate clearly in both languages and interpret Japanese requirements for global teams.
・Collaboration and leadership: Strong interpersonal negotiation and influencing skills; effective working across cultures and in virtual matrixed organizations.
・Autonomy: Able to work independently with limited supervision; demonstrates ownership and follow・through.
・Travel: Willing and able to travel ～25% domestically and internationally.

【Preferred】
・Certifications: Formal auditor training/certification （e.g. GMP Auditor ISO 9001/13485）; quality certifications （e.g. ASQ CQE/CQA） beneficial.
・Sterile and biologics experience: Exposure to sterile manufacturing/Annex 1 biologics vaccines or combination products.
・Technology transfer/validation: Experience supporting technology transfers and process validation activities.
・Regulatory engagement: Direct experience supporting or participating in regulatory inspections （FDA EMA PMDA） and inspection readiness.
・Digital/QMS tools: Proficiency with electronic QMS/LIMS/TrackWise or similar systems; strong Excel and data analysis skills for KPI trending and reporting.
・Continuous improvement: Demonstrated ability to simplify processes implement systemic CAPA and drive sustainable improvements.

Company Description

ご紹介時にご案内いたします