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【年収最大1,000万円】品質保証マネージャー｜グローバルな医療機器・IVD企業での責任者ポジション（ハイブリッド勤務）

> 【年収最大1,200万円】品質保証マネージャー｜グローバルな医療機器・IVD企業

Job Information

Recruiter
Michael Page

Job ID
1529291

Industry
Medical Device

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
8 million yen ~ 10 million yen

Refreshed
March 28th, 2025 18:13

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

- A leading global healthcare company is seeking a QA Manager to oversee quality operations for IVD manufacturing and distribution. This role offers a broad scope across QMS management, regulatory compliance, post-market activities, and leadership of internal audits and quality assurance processes.

Client Details

- This confidential client is an internationally recognized player in the healthcare industry, known for its commitment to innovation and compliance excellence. With a strong presence in Japan and a global support network, they provide opportunities for growth, cross-functional collaboration, and a clear pathway to leadership within a stable yet forward-thinking environment.

Description

- Lead and maintain QMS operations in line with PMD Act and ISO standards
- Manage audits, inspections, and regulatory documentation (labels, SDS, inserts)
- Oversee post-market surveillance, complaint handling, vigilance reporting
- Execute product release decisions and improve product quality with manufacturers
- Support RA tasks including license renewals, applications, and approvals

- Serve as the Responsible Person for IVD manufacturing, sales, and hazardous substances
- Monitor domestic logistics centers and collaborate with global RAQA teams
- Conduct training on regulations and support import documentation
- Participate in strategic cross-functional projects and continuous improvement

Job Offer

- Base Salary: Up to ¥10 million (depending on experience)
- Work Style: Hybrid flexibility (Tokyo or Chiba office)
- Global Exposure: Direct collaboration with overseas RA/QA and manufacturing teams
- Career Growth: Strategic role with potential to expand responsibilities across APAC
- Culture: Professional yet collaborative environment, with focus on compliance and innovation

To apply online please click the 'Apply' button below. For a confidential discussion about this role please contact Sobi Tantisakchaichan on +81357337165.

Required Skills

- Licensed Pharmacist with a Bachelor's degree in Pharmacy (required)
- Experience in QA for IVD or Medical Device companies
- Strong knowledge of QMS, PMD Act, and IVD regulations
- Laboratory and regulatory experience preferred
- Business-level English communication skills
- Detail-oriented, proactive, and strong stakeholder communicator
- Comfortable working independently and in a cross-cultural global setting

Company Description

Job Summary
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