



QA Specialist

Job Information

Recruiter

[Cornerstone Recruitment Japan K.K.](#)

Job ID

1522064

Industry

Medical Device

Job Type

Permanent Full-time

Location

Japan

Salary

5 million yen ~ 10 million yen

Refreshed

September 1st, 2025 04:00

General Requirements

Minimum Experience Level

Over 3 years

Career Level

Mid Career

Minimum English Level

None

Minimum Japanese Level

Native

Minimum Education Level

Bachelor's Degree

Visa Status

Permission to work in Japan required

Job Description

Daily Duties**1. Quality Assurance for Products:**

- Ensure the efficacy, quality, and safety of medical devices manufactured in Japan and overseas.
- Handle quality-related tasks for new product introductions and product modifications, including change management.
- Conduct discontinuation procedures for items, manufacturers, or part numbers.

2. Quality-Related Tasks:

- Coordinate test samples and oversee validation reviews.
- Update packaging and sterilization agreements, arrange sterilization tests, and review catalogs and guides.
- Maintain regulatory data in the QAD system.
- Collaborate with overseas stakeholders for quality-related activities.

3. Non-Conformity and Complaint Handling:

- Address non-conformities and product complaints to prevent the spread of defects.
- Implement measures to improve product quality.

4. Regulatory Compliance:

- Manage documentation required by the Pharmaceuticals and Medical Devices Act and ISO13485.
- Ensure seamless business operations and compliance.

5. Additional Tasks:

- Respond to inquiries, process invoices, conduct audits, and handle ad hoc projects.
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Required Skills

Required Skills & Experience:

- Expertise in quality management systems (ISO13485) and the Pharmaceuticals and Medical Devices Act.
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Company Description