



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

March 31st, 2025 01:00

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