



## 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**

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### 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