



## QA Specialist

### 募集職種

#### 人材紹介会社

Cornerstone Recruitment Japan 株式会社

#### 求人ID

1522064

#### 業種

医療機器

#### 雇用形態

正社員

#### 勤務地

日本

#### 給与

500万円 ~ 1000万円

#### 更新日

2026年02月18日 07:00

### 応募必要条件

#### 職務経験

3年以上

#### キャリアレベル

中途経験者レベル

#### 英語レベル

無し

#### 日本語レベル

ネイティブ

#### 最終学歴

大学卒：学士号

#### 現在のビザ

日本での就労許可が必要です

### 募集要項

#### 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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スキル・資格

**Required Skills & Experience:**

- Expertise in quality management systems (ISO13485) and the Pharmaceuticals and Medical Devices Act.
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会社説明