

## **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

2025年11月26日 13:01

## 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.

# スキル・資格

## Required Skills & Experience:

• Expertise in quality management systems (ISO13485) and the Pharmaceuticals and Medical Devices Act.

会社説明