



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12月24日 09:01

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