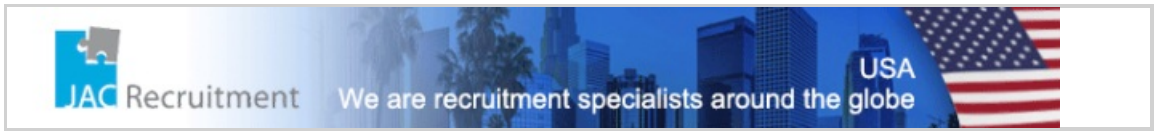
CareerCross by JAC Recruitment



PR/086557 | Senior Regulatory Affairs Specialist (East-Coast / Full-Remote)

Job Information

Recruiter
JAC Recruitment USA

Job ID
1517569

Industry
Medical Device

Job Type
Permanent Full-time

Location
United States

Salary
Negotiable, based on experience

Refreshed
April 8th, 2025 06:00

General Requirements

Minimum Experience Level
Over 3 years

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Business Level

Minimum Education Level
Associate Degree/Diploma

Visa Status
No permission to work in Japan required

Job Description

POSITION SUMMARY

The Senior Regulatory Affairs Specialist is responsible for preparing and submitting regulatory documentation for the marketing of new or modified medical devices in accordance with U.S. regulations.

RESPONSIBILITIES

- Prepare documentation to file 510(k), De Novo, PMA, and Pre-Sub to the FDA and submit to the FDA.
- Prepare and submit documentation to respond to additional requirements by the FDA.
- Liaise and negotiate with regulatory affairs consultants and the FDA.
- Communicate and collaborate with regulatory affairs members in Japan.

- Devise submission strategies for new products to obtain clearance.
- Stay informed about legislation, guidelines, and regulations related to regulatory affairs in the U.S.; inform and advise the team in Japan.
- Ensure that products and related documents conform to the latest medical product regulations.
- Monitor expiration dates of licenses and apply for license renewals.
- Respond to audits by the FDA as needed.
- Participate in medical industry activities, seminars, and conferences related to regulatory affairs.

QUALIFICATIONS

- Bachelor's degree and a minimum of 3 years of related experience.
- Knowledgeable in FDA regulations related to medical devices.
- Effective verbal and written communication skills.
- Strong interpersonal skills.
- Proficient in Word, Excel, and PowerPoint.
- Previous direct experience in medical device regulatory affairs.
- Ability to travel internationally as required.

COMPETENCIES

- Communication proficiency
- Active thinker and actor
- Problem-solving and analysis
- Self-management
- Cooperativeness

SALARY USD130,000-200,000(Yearly Bonus Included)

LOCATION Fully Remote Work

(From East Coast Only)

We sincerely apologize, but due to a high volume of applicants, only those who successfully pass the initial screening will be contacted. We truly appreciate your understanding.

#LI-JACUS #LI-US #countryUS

Company Description