



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

募集職種

人材紹介会社
JAC Recruitment USA

求人ID
1517569

業種
医療機器

雇用形態
正社員

勤務地
アメリカ合衆国

給与
経験考慮の上、応相談

更新日
2025年01月28日 10:34

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
ビジネス会話レベル

日本語レベル
ビジネス会話レベル

最終学歴
短大卒：準学士号

現在のビザ
日本での就労許可は必要ありません

募集要項

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

会社説明