



## 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04月08日 06:00

### 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  
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

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会社説明