PR/086981 | RA specialist

Job Information

Recruiter
JAC Recruitment USA

Job ID
1563251

Industry
Medical Device

Job Type
Permanent Full-time

Location
United States

Salary
Negotiable, based on experience

Refreshed
December 23rd, 2025 13:00

General Requirements

Career Level
Mid Career

Minimum English Level
None

Minimum Japanese Level
None

Minimum Education Level
Associate Degree/Diploma

Visa Status
No permission to work in Japan required

Job Description

POSITION TITLE Regulatory Affairs Assistant

POSITION SUMMARY

A global medical device company is seeking a Regulatory Affairs Assistant to support regulatory submissions in the United States and Canada. This role offers the opportunity to work in a cross-functional, international environment, including collaboration with regulatory teams in Japan. Ideal for professionals with experience in regulatory affairs who are looking to grow their career in a dynamic and global setting.

RESPONSIBILITIES

- Assist in preparing and submitting regulatory documentation for FDA and Health Canada
- Organize, review, and manage submission materials in compliance with regulatory standards

- Support the development and maintenance of departmental policies and procedures
- Maintain accurate and compliant regulatory files
- Prepare meeting materials and assist in presentations
- Communicate effectively with international regulatory teams
- Provide administrative and operational support to the Regulatory Affairs Director

QUALIFICATIONS

- 3+ years of experience in regulatory affairs, preferably in the medical device or healthcare industry
- Knowledge of FDA and Health Canada regulatory processes
- Strong communication skills in English; Japanese proficiency is a plus
- Excellent organizational and time management skills
- Ability to work independently and collaboratively in a global team
- Proficiency in Microsoft Office (Word, Excel, PowerPoint)

LOCATION Irvine, CA (Hybrid work)

SALARY USD80,000-100,000

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Company Description