PR/086904 | Regulatory Affairs and QA Supervisor (Onsite in San Diego, CA)

Job Information

Recruiter
JAC Recruitment USA

Job ID
1556803

Industry
Medical Device

Job Type
Permanent Full-time

Location
United States

Salary
Negotiable, based on experience

Refreshed
September 30th, 2025 09:01

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

Regulatory Affairs and QA Supervisor (Onsite in San Diego, CA)

A Medical device manufacturing company is looking for a Regulatory Affairs and QA Supervisor (or Specialist). This position is primarily responsible for overseeing all Regulatory and QA functions for the company by the following duties. Reporting to the CEO.

RESPONSIBILITIES

- Facilitates audits by interacting with FDA, ISO, and international regulatory bodies.
- Manages the 510k regulatory submission process by compiling and submitting the necessary reports and documentation to internal and external submission partners.
- Works closely with Quality and the Risk Management team to identify and mitigate risk/issues.
- Files Vigilance Reports or MDR (Medical Device Report) to Competent Authority or FDA.

- Interacts between departments to coordinate and facilitate submissions.
- Maintains full awareness of all regulatory activities on assigned projects and ensures that project deadlines and performance standards for these projects are established and met.
- Works to minimize regulatory issues and helps prevent unnecessary regulatory delays.
- Evaluates changes to regulatory documents and formulates a strategy to ensure proper filing categories.
- Plan and implementation and maintenance of the QMS.
- Conduct internal audits to ensure compliance.
- Manage quality control over the entire submission lifecycle, including all component tracking, workflow execution and issue resolution.
- Evaluate changes and signs-off on change control documents, ensuring the correct filing category.
- Represent Quality Assurance on project teams interdepartmentally.
- Performs other duties, as assigned, or as business needs require.
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REQUIREMENTS

- Minimum 3 years of QA/RA experience required
- Bachelor's degree from four-year college or university; or 3+ years related experience and/or training
- Japanese language skills (Preferred)
- Excellent understanding of Food and Drug Administration (FDA) and international organization for standardization (ISO) regulations
- To perform this job successfully, an individual should have knowledge of: Database Software (EPDM); Spreadsheet Software (Excel); Project Management Software; Word Processing Software (Word); Electronic Mail Software (Outlook); Presentation software (PowerPoint).
- Regulatory Affairs Certification Program (Preferred)

SALARY & BENEFIT

- USD 90,000 - 110,000 DOE
- Comprehensive health benefits, 401k, PTO
- Onsite in San Diego, CA
- This role is NOT visa sponsored

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Company Description