Title

Regulatory Affairs Associate

Job Type

Full-Time

The Regulatory Affairs Associate will assist the regulatory affairs team with formatting, assembling and timely preparation of documents for domestic and international regulatory submissions and ensuring compliance with applicable regulations. She/he will be responsible for supporting global regulatory partners to help fulfill regulatory requirements in different countries. Maybe be assigned other regulatory-related duties.

BioFire Diagnostics, LLC. is looking for a Regulatory Affairs Associate to join our growing team! The Regulatory Affairs Associate will assist the regulatory affairs team with formatting, assembling and timely preparation of documents for domestic and international regulatory submissions and ensuring compliance with applicable regulations. The associate will also ensure accurate population of regulatory affairs document databases for tracking global product registrations with most recent and reliable source documents. She/he will be responsible for supporting global regulatory partners to help fulfill regulatory requirements in different countries. Maybe be assigned other regulatory-related duties.

Principal Job Duties and Responsibilities:

- Prepare and submit U.S regulatory submissions [Pre-Submissions, 510(k)s, direct de novo applications, etc.]
- Prepare and maintain product Technical files for CE marking
- Analyze and understand regulatory requirements, and identify solutions; provide directions for proper implementation
- Organize and prepare documents for international submissions. Coordinate with international counterparts to obtain product approvals and renewals
- Conduct research on regulatory changes and developments on application requirements
- Support review of labeling and marketing materials
- Maintain current knowledge of existing and emerging regulations, standards, and guidelines. Assist in keeping the company informed of these requirements
- Interpret regulatory rules, assess rule changes, and ensure their proper communication through corporate policies and procedures
- Review and assess product change impacts (device/labeling) for US and international markets and craft regulatory notification plans
- Assist in the development and review of corporate and department procedures
- Prepare and direct timely preparation of additional information and responses requested by regulatory agencies

Minimum Qualifications

- Bachelor’s degree in biological sciences.
- 1-2 years of experience in Regulatory Affairs in a medical device or in vitro diagnostic device industry.
- Ability to work effectively with multiple disciplines and personalities.
- Demonstrate initiative and have the ability to work both independently and collaboratively in a team structure.
- Understanding and familiarity with FDA & European regulatory requirements, guidelines, and expectations.
- Strong attention to quality/detail.
- Strong interpersonal and communication skills (written and verbal).
- Ability to handle multiple tasks and priorities.
- Proficient with computer and standard software programs (Microsoft Office, Adobe Pro)
- Excellent organizational, time management and administrative skills.