Regulatory Specialist-Remote Based

Hiring organization
BioLink360.com

Employment Type
Full-time

Beginning of employment
2021

Industry
Medical Device

Job Location
Warsaw, IN
Remote work from: USA

Date posted
November 2, 2021

Description

Regulatory Affairs Specialist-EU MDR
Remote Based

Our client is an industry leading Regulatory and Quality consulting company that has consistent year over year growth, and is on a major upswing with Regulatory Affairs hiring. They work with startups to fortune 500 device companies, and there is a lot of variety with client projects.

These are full-time, permanent hire, remote based positions. This is the regular business model, and has been for many years. Typically you will be fully integrated with client teams, and work with their internal teams to meet project deliverables.

I can send you company details and links, but here are a few bullet points:
-Women owned business, 10 years established. The owners still work in the business with clients and employees.
-There's always an expert on the team, lots of room to do new things with new technologies, projects and clients.
-Our Associates love working here! Over 30% of hires this year alone were Associate referrals.
-Some travel to client sites will be required, it's minimal.
-Unlimited time off. Business closes for winter holiday. Work/Life balance is a real thing here.

JOB SUMMARY:
The Regulatory Affairs Specialist works with a team to develop and execute international strategies for regulatory approval of medical device products. The person in this role will work as assigned in these areas, based on skills and experience:

• Coordinates, compiles and submits U.S, and/ or International regulatory submissions, including filing and/or creation of PMAs, IDEs, Premarket Notifications, Supplements, Change Notifications, and other country-specific product registrations.
• Develop IDE/ 510K/ PMA (US) and Technical Files/ Design Dossiers (EU) submissions for class II and III medical devices.
• Manages the generation of documentation to be submitted to worldwide governmental regulatory agencies in order to secure approvals to market products
•Carries out Post Market Surveillance activities such as CAPA support, post market risk management, recalls, and complaint handling.
• Handling submissions (PMA, 510ks, de novo, IDE, HDE, products)
Supporting basic and advanced market entrance, providing acquisition due diligence, UDIs, and clinical evaluation reporting (CERs).
• Reviews device labeling and marketing materials for compliance with FDA submissions and applicable regulations.
• Represents department on cross-functional product development and manufacturing support teams. Guide teams to provide content for US and/or International submissions, participates in design reviews as needed.
• Communicates with and maintain productive, constructive relationships with external customers as required – US FDA, Health Canada, in-country regulatory representatives, and notified-bodies.
• Participate in project development teams and review plans, reports, risk management and design reviews associated with product and process projects.

• Assist in regulatory due diligence for potential and new acquisitions
• Anticipate regulatory obstacles and emerging issues throughout the product lifecycle and develop solutions with other members of regulatory and related teams

About Company Client:
The top 3 reasons people like working here are:
-Work/life balance. It's a real thing. Business closes over Winter Break (it's paid time off).
-Variety. There are hundreds of projects underway with companies globally. You get to work with different device manufacturers without having to change employers.
-Challenge. The opportunity to be entrenched with client teams and a service delivery team to solve device technology's biggest regulatory and quality hurdles
-The people! The interviewing process is unique, as the company is focused on the right fit for all candidates. The interview is a 2 way street and the culture embraces transparency.

Responsibilities
MINIMUM QUALIFICATION REQUIREMENTS

Education
• Bachelors degree, or equivalent of education and experience sufficient to successfully perform the essential Bachelor's degree required: bio-medical engineering or the life sciences highly preferred.
• Regulatory Affairs Certification (US or EU) preferred
• RAPS certification preferred

Experience
• 1-10 years of direct experience in regulatory and/or quality assurance, specific to medical devices.

Skills
• Works with others as a team player to successfully achieve strategy. Must be cooperative and work well with all functional groups.
• Initiative and ability to be self-directed, while thriving in a setting requiring collaboration and teamwork for maximal efficiency and effectiveness
• Ability to effectively respond to time sensitive issues and meet deadlines
• Ability to anticipate, quickly address and make correct decisions in a fast-paced, dynamic environment
• Ability to focus on multiple projects and re-establish priorities as necessary

Job Benefits
Full Corporate Benefits including:
401K, annual bonus, unlimited time off, EAP program, etc.