



<https://www.biolink360.com/job/regulatory-affairs-specialist-associate-to-senior-level-remote-based/>

## Senior Regulatory Specialist-remote based

### Description

Regulatory Affairs Specialist  
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.

We are interviewing candidates with 2-10 years of medical device RA positions, for a number of roles with this fast growth company. We will also speak with Contractors who are looking for full time Contract roles.

These are full-time 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.

Organization accolades include:

- 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

### Hiring organization

BioLink 360

### Employment Type

Full-time

### Beginning of employment

2021

### Industry

Medical Device

### Job Location

Minneapolis, MN

Remote work possible

### Date posted

December 11, 2020

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:

- Grew Regulatory and Quality teams by double digits in 2018 & 2019.
- Has a retention rate of over 95%.
- Hiring for direct hire roles, but may consider Contractors also.
- Offers generous company benefits to include health, dental, and vision insurance, 401K and disability insurance.

## **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.