Medical Device Regulatory Affairs Intern- Portland, Oregon (Remote)

Job Description

We have a vision of a world where people globally have access to a wide range of safe and effective medical devices which is made possible by accurate and timely regulatory support for our clients. With ever changing guidelines throughout the world, it has become increasingly complicated to get a novel device approved for sale globally. For this to change, our clients need expert and trustable guidance with a quick turnaround. We are a company built on a foundation of challenging the status quo of how both employees and clients work together and grow efficiently by providing the highest level of customer satisfaction and success.

Mittal Consulting is seeking a Regulatory Affairs intern to help build regulatory process tools and assist with our workload of upcoming projects. We're looking for someone to quickly embed themselves in the industry, showcase an entrepreneurial candor and develop a strong regulatory work ethic. If you are looking for a foot in the door for the Regulatory world- this is your opportunity!

Responsibilities

- Learn about and gain a deep understanding of FDA and global regulations for medical devices.
- Assist in building regulatory training modules using the latest guidance.
- Help develop process flows for common types of FDA submissions.
- Assist in the compilation of tech files/ design dossiers to notified bodies under new EU MDR regulations with guidance.
- Help in preparation of PMA, 180 DS, RTR, 30 DN, 510(k) and De Novo submissions to the FDA as required with guidance.
- Ensure FDA Readiness of technical documents by checking that they are complete and accurate.
- Perform quality control (QC) review of regulatory submission documents, i.e., grammatical/spelling, formatting, flow and language and general clarity of text.
- Verify that documents meet all applicable regulatory submission standards
- Maintain product submission planners, submission timelines, and logs.

- Recommend enhancements to company procedures in response to changes in regulations or standards or to increase process efficiency.

Position Requirements & Experience

- A minimum of a bachelor's and or undergraduate degree in biological, chemical, engineering, regulatory sciences or writing and communication is required
- Willingness to learn and having an open mind to figure out problem given the resources available.
- Ability to work independently with limited oversight.
- Proficiency in Adobe, Microsoft Suite
- Knowledge of EU and FDA regulations is preferred.
- Strong attention to detail with the ability to multi-task and handle multiple responsibilities simultaneously.
- Excellent organizational skills and an ability to prioritize effectively to deliver results within reasonably established timelines.
- Ability to work independently and as part of a team.

Work Environment and Details

- Remote position (Headquarter is in Portland, OR)
- Flexible Hours (10-20) hours+ per week starting out with ability to increase hours as desired)
- 1099 contract position
- Contractor to provide their own office supplies including laptop.
- Work specific software licenses will be provided (Email, Zoom, Microsoft, CRM etc as required)
- Travel will be reimbursed as required.