infinite biomedical technologies

POSITION: REGULATORY AFFAIRS INTERN

Position Summary:

We are looking for a Regulatory Affairs Intern to support our QA/RA efforts in a close-knit startup environment that values entrepreneurship, individual drive, and delivering immediate impact to patients in need.

About IBT:

Infinite Biomedical Technologies (IBT) is a small medical device company that spun out of Johns Hopkins University and has been in existence for 23 years, maintaining an active research and development program in collaboration with researchers from multiple University. Our mission is to develop innovative medical devices that functionally improve the lives of patients. Our the past decade we have focused exclusiving on developing technology at the interface between people with upper limb amputations and their prostheses. We carry out research, develop in house technology as well as carry out experimental and clinical testing. We have a unique approach that starts from our ability to connect with patients and care providers to determine individual needs. To date, we've launched 4 products in the field of prosthetics, with over 3000 patients served and sales to over 60 unique clinics in the US and distributors in 31 countries.

The Candidate:

At the core, we are looking for an organized and hard-working individual. You should be passionate about creating and managing documentation for global regulatory submissions. You should also be excited about understanding and adapting to changing standards and regulations. Must be comfortable with a fast-paced environment and driven by ensuring regulatory compliance across all of IBT's products.

Prior regulatory and quality experience is strongly weighted. You should have high standards for your work and be very organized in your approach to your job. You will be expected to generate high quality documentation, will need to be meticulous and must be able to meet stringent deadlines. You will need to thrive in start-up environment, where you'll be prepared to learn on the go while managing your own day-to-day activities. At the same time, you should not be on an island. At IBT, people are encouraged to over-communicate, raise concerns, and bounce ideas off of each other constantly.

What you will do:

- Create, manage and update regulatory documentation to be compliant with FDA and EU regulations
- Participate in post market surveillance activities and identify updates to risk management
- Participate in writing and running of protocols for verification and validation activities
- Creation of documentation for regulatory filings of new product development – Technical File for CE Marking, Pre-submissions and 510k Submissions for FDA

What you'll need for this position:

Education:

- Undergraduate degree with basic experience in medical devices

Must-have skills & experience:

- Significant experience in producing high quality technical documentation
- Strong written and verbal skills
- Organized and hard working

- Able to meet stringent deadlines
- Pride in doing amazing and impactful work
- Action and detail oriented

Nice to have skills/experience:

- Familiarity with the following:
    - ISO 14971: Risk Management
    - Technical File for CE Marking
    - Pre-submissions and 510k Submisisons for FDA

What's in it for you:

- ***Work with passionate people:*** You will work with people who genuinely care about helping improve peoples' lives. That includes your co-workers and your customers.
- ***Work closely with cutting edge technology***: such as multi-articulated prosthetic hands, flexible electronics, and small form factor/low energy components.
- ***Gain experience in regulatory activities for medical devices***: You will gain first hand experience in creation of documentation for getting approvals from global regulatory bodies as well as for maintaining complaince.
- ***Work in a close-knit, startup environment***: We strive to create an intellectually stimulating and collegial working environment. We follow the philosophy of "work hard, play hard": we have regular movie nights, board game nights, plan field trips, eat good food, and generally have a good time.
- ***An opportunity for full-time employment*:** At the conclusion of your internship, there may be an opportunity to join our company as a full-time employee if there's a good mutual fit.
- ***Compensation:*** stipend of $20/hour. Looking for commitment of 15-20 hours/week for 3-6 months.

Still Interested? To apply, please send send a PDF resume and any relevant information (images, videos) via email to careers@i-biomed.com. More info can be found at www.i-biomed.com.