



## POSITION: QUALITY AND REGULATORY ENGINEER

### Position Summary:

We are looking for a Quality and Regulatory Engineer 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. Over the past decade we have focused exclusively 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 2800 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 building safe and high quality medical devices. You should also be excited about understanding and adapting to changing standards and regulations. In this role you will be tasked with creating and managing documentation for a medical device Quality Management System (QMS) as well as for global regulatory submissions. You must also be comfortable in a fast-paced environment and driven by improving QMS processes and ensuring regulatory compliance across all of IBT's products.

Prior experience with medical device engineering is a must, since you will be working with cutting-edge electronic, mechanical, and software 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 maintain multiple roles and responsibilities and 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 QMS processes to be compliant with relevant standards
- Create, manage, and update regulatory documentation to be compliant with global regulations
- Stay informed on updates to standards and regulations and create internal timelines for transitions
- Review updates in standards and regulations, perform gap analysis and present transition plan to management
- Determine requirements and regulatory pathway and create documentation for regulatory filings of new product development
- Review documentation from product development, production and manufacturing and post market surveillance to evaluate compliance to QMS processes
- Schedule and perform vendor qualifications & equipment calibrations

- Participate in creation and conduct of internal and external audit activities
- Participate in post market surveillance activities and improve data analysis for trend tracking – complaint handling, CAPAs, non-conformances
- Create and conduct QMS trainings for team
- Establish and maintain relationships with regulatory points of contact
- Participate in writing and running of protocols for verification and validation activities

### What you'll need for this position:

#### Education:

- Undergraduate degree in an engineering field

#### Must-have skills & experience:

- Quality and regulatory experience for medical devices
- Significant experience in 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 13485:2016
  - ISO 14971:2019
  - FDA Pre-Submissions, FDA 510(k) applications and De-Novo Submissions
  - EU MDR, EU Technical File
  - 21 CFR Part 820 – Current Good Manufacturing Practices (cGMP)
  - IEC 60601, ISO 15223, IEC 62366, ISO 10993, IEC 62304
  - MDSAP
- Prior experience in QMS documentation for Class I and Class II FDA devices
- Prior experience with FDA audits

### 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 quality and regulatory activities for medical devices:** You will gain first hand experience in setting up a compliant QMS and getting approvals from global regulatory bodies.
- **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.

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