infinite biomedical technologies

POSITION: QUALITY MANAGER

Position Summary:
We're looking for an experienced Quality Manager to ensure our products are of the highest quality before reaching our customers. In this role, you will be primarily responsible for maintaining our quality systems for our electronic arm prosthesis product line. In this role you'll be involved in the development of new cutting edge products along with our fast-paced engineering team as well as maintaining and supporting existing products on the market. You will be working closely with operations, customer service, test engineering, technical operations, and contract manufacturers. Our ideal quality manager has strong interpsonal skills, is meticulous, and takes pride in selling quality products.

About IBT:

Infinite Biomedical Technologies is a small medical device company that spun out of Johns Hopkins University and has been in existence for 20 years, maintaining an active research and development program in collaboration with several University researchers. Our mission is to develop innovative medical devices that functionally improve the lives of patients. Currently, we are developing technologies at the interface between a person's limb and their prostheses. These technologies include surface EMG electrodes, flexible batteries, virtual training systems, decoding algorithms, wireless object recognition, and novel mechanical interfaces. 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 upper limb prosthetics, with over 1000 patients served in 26 countries.

What you'll be doing:

- Maintaing the company's Quality Management System
- Develop, administer and maintain quality assurance procedures and activities required to ensure that the company's processes and products are in compliance with applicable quality standards and requirements
- Employ quality assurance methodologies in support of engineering, manufacturing and regulatory functions
- Develop and implement quality control and inspection procedures for receipt and control of incoming materials, in-process materials and final product acceptance activities
- Define quality control standards and test; specify test equipment and procedures
- Establish and maintain test instrument calibration procedures and maintenance schedules
- Set requirements for raw material or intermediate products for suppliers and monitor their compliance
- Establish quality assurance and quality control inspection and testing procedures
- Identify quality assurance metrics; analyze and report trends to management
- Review and host meeting(s) for nonconforming materials.
- Active participant in all stages of design development, V&V testing and design control activities, ensuring quality assurance considerations and requirements met
- Participate in the review of product requirements, design requirements, software requirements specifications, and functional specifications
- Understand customer needs and requirements to develop effective quality control processes
- Solicit feedback from customers to assess whether their requirements are met
- Be on the lookout for opportunities for improvement and develop new efficient procedures
- Complaint handling
- Assist in Risk Management activities, FMEAs and ensure compliance to standards and regulations
- Assist in preparation for and conducting of regulatory agency inspections
- Review for completeness and adequacy of the Design History records

What you'll need for this position:
Education:

- BS or MS degree in Engineering

Must have skills & experience:

- Successful candidates will have the following attributes: strong interpersonal skills and ability to communicate with people outside of the field; exceptional ability build and maintain relationships; strong documentation skills, especially writing clear test plans and reports; detail-oriented and organized; enthusiastic and motivated
- 1+ years of industry experience in one or more of the following disciplines: Product Quality, Manufacturing Operations, Design Engineering, Regulatory Affairs
- Experience or knowledge in test engineering, reliability engineering and supplier quality engineering
- Experience developing process quality plans, driving corrective actions and failure analysis efforts.
- Thorough knowledge of ISO 13485: 2003 (Quality System) requirements and Good Manufacturing Practices (GMP)

Nice to have skills/experience:

- Knowledge or familiarity with ISO14971 (Risk Management) requirements, Medical Device Directives (MDD) requirements.
- Experience with EN 60601 (Safety requirements for medical electrical system) testing
- Familiarity with ISO 62304, Medical Device Software – Software Life Cycle processes
- Ability to analyze and interpret standards, technical procedures, professional journals and governmental guidance and regulation documents
- Understanding of material biocompatibility requirements
- Experience with any of the following: mechanical parts, castings, plastic parts, injection molding, tooling, jigs, or fixtures

What's in it for you:

- ***Work closely with cutting edge technology***, such as multi-articulated prosthetic hands, flexible electronics, and small form factor/low energy components.
- ***Be independent and creative****:* At IBT you won't be just another cog in the machine. You will be treated as an equal and your opinions will be respected. You will be given the room to develop creative solutions. Succeed and you'll quickly move up to a leadership position within the company.
- ***Help people in need***: At IBT, one of the biggest rewards is that the technology we build will directly impact patient lives. You will be integral in improving the functionality of a patient population very much in need.
- ***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 annual retreats, regular movie nights, ping pong tournaments, plan field trips, play touch football, play music, and generally have a good time.
- ***Launch innovative products***: We pride ourselves in pushing the boundaries of technology for our customers. Our close relationships with some of the top-ranked research institutions in the world allows us to bridge the gap between what's possible and what's available to our customers.
- ***Learn new skills:*** We want you to do what you do best, but that doesn't mean you'll stop developing new skills. Where we don't have internal experience, we have access to brilliant consultants with years of experience in quality assurance and regulatory science to help supplement you. We also encourage all of our employees to attend conferences and take advantage of professional education regularly.
- ***Compensation:*** Competitive based on experience and skills to start with full health (general, dental, vision), 401(k), and a generous vacation policy.
- ***Relocation/sponsorship*** may be provided.

Still Interested? To apply, please send a personalized cover letter to Rahul Kaliki, PhD, CEO of IBT, explaining why you'd be a great fit for this role and what you can offer IBT. Also send a PDF resume and any other relevant information that could help us get to know you better via email to careers@i-biomed.com. More info can be found at www.i-biomed.com.