Job title Edit

Design Quality Engineer

Company Edit

WishBone Medical, Inc

Job location Edit

100 Capital Drive
Warsaw, IN 46582

Visible on job post: Yes
Remote work allowed: No

Advertising location

Warsaw, IN 46582

Additional advertising locations Paid feature

Fort Wayne, IN

Columbia City, IN

Job Type Edit

Full-time

Job description Edit

JOB TITLE: Design Quality Engineer

SUMMARY: The position is responsible for developing, establishing, and maintaining risk management files for all new product development of orthopedic implants, instruments, and packaging. The Design Quality Engineer also participates in CAPA activities, quality initiatives, as well as post-market engineering activities. WishBone Medical is a small start-up and this position will provide an opportunity to make a difference for the company long-term.

ESSENTIAL DUTIES AND RESPONSIBILITIES *(include the following. Other duties may be assigned.)*

- Facilitate risk management activities throughout all design phases
- Work with product development and design engineering in the completion of product verification and validation activities
- Work with product development, design, and supplier quality in definition of CTQs

- Apply sound, systematic problem-solving methodologies in identifying, prioritizing, communicating, and resolving quality issues
- Support development of US FDA submission requirements
- Support all Company initiatives as identified by management and in support of Quality Management Systems (QMS), Environmental Management Systems (EMS), and other regulatory requirements. May serve as coordinator in quality initiatives.
- Support Quality Improvement projects for the site, including formal quality efforts such as CAPA, NCMR, and Audit Responses.
- May assist with complaint analysis and trending in support of post-market surveillance. Supports post market / sustaining engineering efforts on commercialized product.
- Support Health Risk Assessments (HRAs) to ensure risk assessment and root cause analysis are consistent across products and systems.
- Complies with U.S. Food and Drug Administration (FDA) regulations, other regulatory requirements, Company policies, operating procedures, processes, and task assignments
- Maintains positive and cooperative communications and collaboration with all levels of employees, customers, contractors, and vendors
- Performs other related duties and responsibilities, on occasion, as assigned

QUALIFICATION REQUIREMENTS

- BS in Engineering (preferred), science or technical field.
- 2-5 years of work experience in the medical device industry is preferred.
- Experience with FDA requirements 21 CFR 820, knowledge of regulations such as GLP, GMP, ISO 13485 and ISO 14971, as well as other international regulatory requirements is a nice to have.
- Experience in related areas, e.g. R&D or Manufacturing may also be applicable if experience includes work responsibilities listed above.

PHYSICAL DEMANDS: The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is regularly required to sit and talk or hear. The employee frequently is required to stand; walk; and use hands to finger, handle, or feel objects, tools, or controls. The employee is occasionally required to reach with hands and arms. The employee must occasionally lift and/or move up to 20 pounds.

WORK ENVIRONMENT: Teammate will normally work in an office environment but may occasionally be subject to noise levels from machines in a manufacturing environment.

Travel requirements: Up to 5% long-distance travel (i.e. by plane).

Applicant Qualifications Edit

You have requested that Indeed ask candidates the following questions:

- What is the highest level of education you have completed?
- How many years of Medical Device experience do you have?
- Please list 2-3 dates and time ranges that you could do an interview.

Language Edit

English

Expected Hiring Date Edit

1 to 2 weeks

Hires Needed Edit

2

Schedule Edit

8 hour shift, Monday to Friday

Application settings Edit

Apply method: **Email**
Send updates to: **marywetzel@wishbonemedical.com**
Employer Assist: **10 days**

Do you want applicants to submit a resume? **Yes**
Do you want to let applicants start the conversation? **Yes**

Selected Assessment Types Edit

Project timeline management, Basic attention to detail

Job Budget

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