Job title Edit

Manager, Quality Assurance & Regulatory Affairs

Company Edit

WishBone Medical, Inc

Job location Edit

100 Capital Drive

Visible on job post: Yes
Remote work allowed: No

Advertising location

Additional advertising locations Paid feature

Warsaw, IN 46582

Job Type Edit

Full-time

Job description Edit

JOB TITLE: Manager, Quality Assurance & Regulatory Affairs

SUMMARY: Manager of Quality Assurance & Regulatory Affairs is responsible for managing quality assurance and regulatory support for Wishbone Medical. The primary focus is to ensure that the Quality Management System (QMS), Design Quality Assurance and Regulatory Affairs Controls are compliant to current and future USFDA, ISO and MDR Standards and Regulation for Medical Devices, including Sterile Packaging. Quality and regulatory affairs support may be required for additional geographies. This position is also responsible for monitoring and continually improving current QMS, Design Quality, and Regulatory Affairs systems for the effectiveness of execution and compliance.

PRINCIPAL DUTIES AND RESPONSIBILITIES

- Ensures the QMS, Design Quality, and Regulatory Affairs requirements are effectively established and maintained in accordance with medical device regulations and international standards.

- Monitors conformance of the device with the QMS prior to release, ensuring regulatory documentation is prepared and maintained, ensuring post-market surveillance obligations are met, ensuring requirements for submission of vigilance reports are complied with, and compliance of devices used for clinical investigation are documented.

- Directs post market engineering assignments and activities, develops strategies for health risk assessments.

- Communicates with Regulatory/Governmental agencies; including responding to requests from foreign governments and/or distributors to prepare and submit documentation for marketing approval as well as provide routine regulatory information to affiliates.

- Develops systems, implements and trains employees, and manages processes for quality and regulatory requirements including, but not limited to, design quality assurance, corrective and preventative actions (CAPA), quality audits, post market surveillance/vigilance, and recalls/removals.

- Interprets and applies FDA regulations to business practices and provides regulatory input, advise, and guidance to the organization. May author and publish electronic submissions.

- Manages Design Quality and Regulatory Affairs staff on project teams.

- Keeps all areas of WishBone Medical informed of regulatory requirements and emerging issues which may affect the registration approval of products. Assess impact of engineering changes on current regulatory filings.

- Participates in all announced and un-announced QMS/Product audits from the FDA or authorized regulatory authorities. May direct the planning and execution of all internal and external audits.

- Reviews, evaluates, and approves promotion and advertising material for compliance with applicable regulations.

- Responsibility for oversight and prioritization of departmental tasks and projects.

- Miscellaneous responsibilities as assigned

EXPECTED AREAS OF COMPETENCE

- Strong interpersonal, organizational, problem-solving and analytical skills; strong attention to detail.

- Demonstrated strong writing and communication skills; ability to communicate effectively at multiple levels, including with regulatory agencies, superiors, peers, and direct reports.

- Ability to manage competing priorities; ability to manage projects of various sizes, constitutions, and management of personnel; versatility, flexibility, and willingness to work with changing priorities.

- Advanced knowledge of overall business environment, the orthopedic industry and the marketplace; strong product knowledge.

- Must work precisely according to procedures, rules and regulations, has a passion for continuous improvement and quality.

- Able to demonstrate the highest ethical standards, actively promotes trust, respect and integrity in all dealings both inside and outside the Company.

- Mastery of relevant regulations, and ability to stay abreast of regulations pertinent to medical devices, biologics, drugs and combination products as applicable.

- Experience in post market activities, including complaints/MDR and CAPAs.

- Must have service-oriented approach, flexible and proactive towards changing needs; ability to handle increasing levels of responsibility.

- High level of proficiency in Microsoft Word, Outlook, Excel and PowerPoint is essential.

- Advanced knowledge of FDA regulations (including labeling regulations) and regulations outside of the US/EU as applicable.

Experience Requirements

- Bachelor’s Degree or equivalent is required.

- 6-8 years of experience in Quality / Regulatory Affairs.

- A minimum of 3 years of experience in medical device.

- A minimum of 1 year in a management role with direct reports is required.

- A combination of education, experience, leadership, strategy and QA/RA influence may be considered.

Applicant Qualifications Edit

You have requested that Indeed ask candidates the following questions:

Language Edit

English

Expected Hiring Date Edit

2 to 4 weeks

Hires Needed Edit

1

Schedule Edit

8 hour shift, Monday to Friday

Application settings Edit

Apply method: **Email**
Send updates to: **marywentorf@wishbonemedical.com**
Employer Assist: **14 days**

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

Selected Assessment Types Edit

Advanced attention to detail, Analyzing data

Job Budget

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