NEXTSTEP™ ARTHROPEDIX | Career Opportunity

1800 Triplett Blvd. Akron, OH 44306 (330) 733-7600 www.nextsteparthropedix.com

Quality Systems Engineer

LOCATION: Akron, Ohio

JOB SUMMARY

This position will report directly to the Quality Manager. This individual will work closely with the Quality and Engineering teams. This role will help support the development, implementation, and continuous improvement of the Quality Management System.

KEY RESPONSIBILITIES

- Developing and implementing quality standards and quality control systems
- Writing procedures and processes to support the Quality Management System (QMS)
- Monitoring and analyzing quality performance of materials, equipment, processes, and products.
- Inspecting and testing to ensure quality specifications are met
- Auditing systems and supply chain
- Creating and executing test scripts and automated tests
- Communicating with stakeholders and operations managers
- Providing training and championing the QMS
- Participate in Quality reviews and approval of all technical documentation for design and development technical and risk management documentation, e.g., planning, traceability matrix, protocols, reports, risk assessments, testing, etc. through applying applicable company procedures and regulatory requirements.
- Help support compliance with filing and implementing changes through authoring and/or reviewing sections of filing applicable to design control, risk management and specification and supporting responses to regulatory questions with the Quality team.
- Help Implement, support and maintain the eQMS.
- Support the timely handling of investigations, impact assessment, deviations, and CAPAs, and technical matters (i.e. design changes, verification and validation) with impact to design control and risk management or related supply chain operations.
- Help support sustainable, continuous improvement to the device Quality Management System and best practices for device life cycle processes by identifying areas for improvement and engaging in remediation.
- Manage QA interface with medical device or device component suppliers and testing partners by providing technical and quality support during the development, testing and manufacture at supplier sites.
- Help support Supplier monitoring. Support internal and external audits and inspections.

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QUALIFICATIONS

- A minimum of Associates Degree of Engineering, Business or 2+ years of related technical experience.
- Experience or education in medical devices within a medical device, biotech, or pharmaceutical company is a plus.
- Knowledgeable of Quality Management Systems
- Working knowledge and application of device regulations of ISO 13485
- Experience in supplier management and relations, including quality agreement generation and maintenance.
- Working knowledge of process development and validation principles
- Experience in interpreting drawings, GD&T
- Experience in Change Control and CAPA applications
- Demonstrate effective cross-functional and cross-cultural skills.
- Ability to effectively influence others without direct authority and professionally handle conflict resolution.
- Ability to independently represent the department in project teams.
- Demonstrate ability to assess and provide technical and quality guidance to ensure high-quality, compliant devices.
- Demonstrate strong skills to organize, prioritize, and execute. Must be detail-oriented with strong leadership skills and excellent interpersonal, collaboration, and communication skills.
- Must be willing to travel to sister sites on a weekly basis to help support. (Cleveland and Akron areas)

APPLY

Express interest and relevant qualifications via email to **careers@theken.us**. Cover letter and resume welcome.