

Choice Spine Job Description

Job Title: Quality Engineer I

Department: Quality
Location: Knoxville, TN
Reports To: Quality Manager
Shift: First
FLSA Status: Non-Exempt
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Prepared Date: 8/23/2024
Approved By: Becki Davis
Approved Date: xx/xx/2024

SUMMARY

Under supervision from the Quality Manager, the Quality Engineer I will support Quality Assurance activities and assist Quality Control and Regulatory as part of a comprehensive Quality Management System.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Read, understand, and interpret engineering drawings and associated GD&T.
- Perform transactions in ERP system, as necessary.
- Identify non-conforming products and generate non-conformance reports as needed.
- Read and conform to all company policies and procedures.
- Interact and communicate with internal departments, including Purchasing, Shipping / Receiving, Engineering, Customer Service, and Sales / Marketing.
- Create non-conformance reports for non-conforming product.
- Authority to place product on hold.
- Involved with new product development (NPD) process and the support of existing and previously commercialized products.
- Review and approve engineering drawings and assist in determining Critical-To-Quality Dimensions.
- Create, Review, and Approve Inspection Plans and Inspection tools as required.
- Create and Support validations for new and existing products and processes, including packaging and sterilization.
- Create and Support IQ, OQ, and PQ activities for equipment and additive implants.
- Perform and support Gage Repeatability and Reproducibility (Gage R & R) studies.
- Perform and support First Article Inspection / Inspections on Prototypes.
- Perform Statistical rationales as required.
- Support supplier quality management activities, including qualification, evaluation, and investigations.
- Support Post Market Surveillance activities.
- Support Complaint/NC/CAPA teams through the identification and development of corrective action plans, verification, and closure.
- Perform and support Design and Process FMEA activities.
- Collect, analyze, and summarize data and make recommendations as required.
- Support and prepare for site-level internal, external, supplier, and customer audits.
- Provide quality support to identify and resolve quality issues to ensure safe and effective medical devices,
- Interact and coordinate activities with other departments, support, and customers.
- Identify and implement opportunities for continuous improvement.
- Create and update Quality System Procedures and Instructions when applicable.

- Supports Operations when Engineering changes occur.
- Supports internal team to meet company and department objectives.
- Assist in the Calibration program.
- Other duties as assigned by management,

SUPERVISORY RESPONSIBILITIES

Not Applicable

QUALIFICATIONS

- Excellent communication skills and the ability to work with people at all levels.
- Ability to work independently and in a team environment.
- Strong organizational skills, attention to detail, self-motivator, ability to multi-task and meet timelines.
- A working knowledge of desktop computer office software and e-mail is required.
- Understand calibration fundamentals.
- Experience using inspection equipment such as calipers, micrometers, height gauges, plug and ring thread gauges, and pin gauges. Optical comparator and Vision system experience preferred.
- Understanding of SOLIDWORKS or 3D modeling is preferred.
- Knowledge and understanding of Medical Device Regulations / Certifications such as 21CFR820 & ISO13485:2016.
- Medical Device experience is preferred.

EDUCATION and EXPERIENCE

Engineering / Science degree or equivalent and up to 5 years' experience with Quality Management Systems, medical device industry experience preferred.

CERTIFICATES, LICENSES, REGISTRATIONS

Not Applicable

EXEMPTION

Exempt

PHYSICAL DEMANDS

The physical demands described here represent those that an employee must meet to perform the essential functions of this job successfully. Reasonable accommodations may be made to enable individuals with disabilities to perform essential functions.

While performing the duties of this job, the employee is regularly required to sit and talk or hear. In addition, the employee should be able to stand, walk, use hands to finger, handle, or feel and reach with hands and arms. In addition, the employee must occasionally lift and move up to 25 pounds.

WORK ENVIRONMENT

The work environment characteristics described here represent those an employee encounter while performing this job's essential functions. Reasonable accommodations may be made to enable individuals with disabilities to perform essential functions. The working environment is typical of an office environment. The noise level in the work environment is usually moderate.