Choice Spine
Job Description

Job Title: **Senior Quality Engineer**

Department: Quality
Location: Knoxville, TN
Reports To: Quality Manager
Shift: First
FLSA Status: Non-Exempt
Prepared By: Jeffrey McNaughton
Prepared Date: 7/25/2025
Approved By: Steve Ainsworth
Approved Date: 7/28/2025

SUMMARY

Under minimal supervision from the Quality Manager, the Senior Quality Engineer will support Engineering and 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 product 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 .
- 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 Quality, Engineering, and Regulatory to meet company and department objectives.
- 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 organization skills, attention to detail, self-motivator, ability to multi-task and meet timelines.
- 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.experience preferred.
- Experience with Keyence Vision Systems is required.
- Experience in SOLIDWORKS or 3D modeling is required.
- Knowledge and understanding of Medical Device Regulations / Certifications such as 21CFR820 & ISO13485:2016.
- Medical Device experience is required.

EDUCATION and EXPERIENCE

Engineering degree or equivalent and at least 8 years' experience with mechanical inspection of precision machined products, 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.