Choice Spine
Job Description

Job Title:	**Quality Manager**
Department:	Operations
Location:	Knoxville, TN
Reports To:	Director of Operations
Shift:	First
FLSA Status:	Exempt
Prepared By:	David Davis
Prepared Date:	07/29/2019
Approved By:	David Davis
Approved Date:	07/29/2019

SUMMARY

Provides leadership pertaining to quality systems development, compliance auditing, quality and productivity improvement support, and complaint investigations. Manages the quality systems, programs, policies and initiatives, to meet FDA and ISO13485 regulations.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Lead the organization's Quality staff to ensure compliance to the overall Quality Management System and drive Continuous Improvement
- Provide coaching, mentoring and leadership to the Quality staff
- Determine supplier qualification risks based upon criticality of component and supplier process capability
- Manage Supplier Quality and collaborate with Contract Manufacturers
- Perform Supplier Qualification Audits / Internal Audits to 21CFR820 and ISO 13485:2016
- Participate in CAPA / Compliant Investigations
- Ensures the quality assurance programs and policies are maintained and modified regularly
- Assist with Notified Body QS audits, FDA inspections
- Provide guidance and participate where appropriate in Feasibility, Development, Design Verification, Design Validation, Design Transfer activities from a quality and documentation perspective
- Interpret drawings in order to ensure appropriate inspection tools are available based on geometric dimensioning and tolerancing
- Assist and lead validation processes (i.e. develop protocols, IQ, OQ, PQ)
- Participate in FEMA's and Risk Analysis

SUPERVISORY RESPONSIBILITIES

- Manages Quality staff (Inspectors and Technicians)

QUALIFICATIONS

- Proven ability to lead a diverse team of technicians
- Knowledge and understanding of Medical Device Regulations / Certifications such as 21CFR820 & ISO13485:2016
- Excellent communication skills and the ability to work with people at all levels
- Familiarity with manufacturing processes
- Ability to read and interpret mechanical drawings, including GD&T, is strongly preferred
- Experience with Validations is preferred
- Strong organizational, analytic, problem solving, and management skills
- Self-motivated and excellent attention to detail
- Must be able to multi-task and meet timelines
- Medical Device experience is required

EDUCATION and/or EXPERIENCE

- Bachelor's degree in Engineering / Sciences
- Minimum of 7 years of experience in Quality
- 5+ years of managerial experience

CERTIFICATES, LICENSES, REGISTRATIONS

- Current CQA, CQE, or similar certification is preferred

EXEMPTION

- Exempt

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 is occasionally required to stand; walk; use hands to finger, handle, or feel; and reach with hands and arms. The employee must occasionally lift and/or move up to 25 pounds.

WORK ENVIRONMENT

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