Choice Spine
Job Description

Job Title: **Quality System / Document Control Specialist**
Department: Regulatory Affairs
Location: Knoxville, TN.
Reports To: Director of Regulatory Affairs
Shift: 1st
FLSA Status: Non-Exempt
Prepared By: Kim Finch

KNOWLEDGE/SKILLS REQUIRED:

Job Responsibilities:

- **Ensures compliance and timeliness, accuracy of routing and supporting documentation to specifications. Authorized to correct as necessary.**
- **Maintains the integrity of the document control system. Authorized to deny access and to include, replace, revise or make obsolete documents therein. Has the responsibility to confirm the accuracy of Work Instructions, Standard Operating Procedures, Quality Reference Documents, forms and other documents against specifications whenever possible.**
- **Maintains the documentation files in compliance with ISO 13485. FDA 21CFR 820 and 21 CFR Part 11, EU Medical Device Regulations 93/42/EEC, and EU MDR/2017.**
- **Responsible for the formal Quality Systems files to include company DHR's, DMR's and DHF's. Responds promptly, whenever possible to requests for information specific to the quality system documents.**
- **Creates, maintains, and improves controls on all documentation masters, device history records, change orders, design history files both manual and electronic archive.**
- **Maintains and updates the Standards Library.**
- **Interacts effectively with FDA and ISO Registrars and customers prior to and during audits concerning document**
- **Inputs data to create and revise material master / GUDID and Euamed database in the ERP system (SAP).**
- **Performs internal audits as assigned.**
- **Maintains Tissue State Tissue Licenses**
- **Maintains Board of Pharmacy Licenses**

Supervisory Responsibility: N/A
Qualifications:

- **Must have multi-task abilities, self-motivator and solid organizational skills.**
- **Knowledgeable in 21 CFR 820 and ISO 13485, and medical device regulations**
- **Experience working in a regulated industry, preferably ISO 13485.**
- **Good Communication Skills.**
- **Demonstrated problem solving skills.**
- **Working knowledge of desktop computer software, database software, scanning software and email applications.**
- **Must be very detail oriented and accurate with data entry.**

Education and/ or Experience:

- **1-2 years related experience in a regulated field required.**

Signatory Responsibilities Documentation as needed.