Choice Spine
Job Description

Job Title: **Regulatory Specialist 1**
Department: Regulatory Affairs
Location: Knoxville, TN.
Reports To: Director of Regulatory Affairs
Shift: 1st
FLSA Status: Exempt
Prepared By: Kim Finch

KNOWLEDGE/SKILLS REQUIRED

Job Responsibilities:

- Control and maintain regulatory records.
- Ensures compliance, timeliness, and accuracy of routing and supporting documentation to specifications. Authorized to correct as necessary per procedures.
- Maintains the integrity of the document control system. Authorized to deny access and to include, replace, revise, or make obsolete documents therein.
- Maintains the documentation files in compliance with ISO 13485, FDA, 21 CFR Part 820, 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 DHRs, DMRs and DHFs.
- Creates and maintains QMS documentation to support design history records, technical files, change orders, and registration submissions.
- Ability to determine and communicate submission and approval requirements to others.
- Maintains a current standards library.
- Interacts effectively with FDA and ISO registrars and customers prior to and during audits.
- Inputs data to create and revise material master / GUDID and Eudamed database in the ERP system (SAP).
- Performs internal audits as assigned.
- Maintains State Tissue/Board of Pharmacy licenses.
- Schedules training and maintains employee training records.

Qualifications:

- Must be very detail oriented and accurate with data entry.
- Must have effective time management strategies, workload prioritization, self-motivation, and solid organizational skills.
- Knowledgeable in 21 CFR 820, ISO 13485, and medical device regulations.
- Experience working in a regulated industry (ISO 13485 preferred).
- Excellent written and oral communication capabilities.
- Demonstrated analytical and problem-solving skills. Ability to exercise good judgment.
- Computer literacy in Microsoft applications. Working knowledge of electronic Quality Management System (eQMS) (ComplianceQuest preferred), scanning software and email applications.
- Can work independently or with a team.

Education and/ or Experience:

- BS degree or equivalent or 4 years related experience
- 2 -5 years related experience in a regulated field desired