

Choice Spine Job Description

Job Title: Validation Engineer

Department: R&D
Location: Knoxville, TN
Reports To: Director of R&D
Shift: First
FLSA Status: Non-Exempt
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Prepared Date: 03/01/2019
Approved By: Steve Ainsworth
Approved Date: 03/04/2019

SUMMARY

The Validation Engineer is responsible for assuring products and processes conform to established requirements and standards through appropriate audit, inspection, and test activities. Work will be focused on gathering relevant, factual information and data in order to solve quality related problems. Duties will also include authoring and approving procedures and protocols for in-house manufacturing.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Formulate procedures, specifications, and standards for ChoiceSpine products and processes
- Author and execute protocols and reports for IQs, OQs and PQs. Validations will include legacy, new and changed products, processes, systems and equipment (ex: MTS, laser marker)
- Conduct gap analyses and remediation on Design History Files to ensure compliance with external regulations and internal procedures.
- Lead periodic performance/data review of critical equipment and processes.
- Lead cleaning validation and annual monitoring projects.
- Conduct audits of validation and performance qualification processes to ensure compliance with internal and regulatory requirements.
- Manage feedback, CAPA and process improvement projects driving root cause investigation and corrective action implementation.
- Duties to be performed in compliance with applicable regulations and standards including FDA Quality System Regulation 21 CFR Part 820, ISO 13485, and the European Medical Device Regulation.

QUALIFICATIONS

- Familiarity with processes in a manufacturing environment
- Ability to read and interpret mechanical drawings, including GD&T, is strongly preferred
- Strong organization skills, attention to detail, self-motivator, ability to multi-task and meet timelines
- Medical device industry experience preferred

EDUCATION and/or EXPERIENCE

- B.S. in Engineering, and at least 3 years of experience required
- Certification as a quality engineer (e.g. CQE) or the Reliability Engineer Certification (CRE) granted through the American Society of Quality (ASQ) preferred

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 employee must occasionally lift and/or move up to 25 pounds.