QE Validation Engineer, Irvine, CA

Responsibilities

Responsible for maintaining validation program activities including generating protocols, reports and execution of process and equipment validations/qualifications. Create and maintain process flow charts and related PFMEAs (Risk Evaluation). Perform verification and exploratory studies to Execute DOEs and GR&R studies. Responsible for Master Validation Plans, validation standards, develops/performs validation/qualification studies such as IQ, OQ, PQ, SQs, DOEs and GR&Rs associated with new and sustaining product/processes/equipment. Creating/executing validations, qualifications, verifications, and test protocols. Reports must be in scientific method/format. Maintain records and coordinate with various functions including operations, engineering, vendors/suppliers and QARA. Apply risk-based approaches to qualification and validation activities to meet current regulatory requirements that employ statistically valid methodology. Create and revise procedures to ensure alignment with process validation plans. Support QA/Engineering in processing statistical data and support QA in data analysis/trending. Provide engineering lab technician support for Validation Testing. QA/Operational support with PMs, monitoring, testing and quarterly dose audits. Perform duties in compliance with applicable regulatory requirements and company SOPs. Ensure all quality aspects of this position. Maintain a safe working environment.

Qualifications

THIS POSITION REQUIRES A BACHELOR'S DEGREE OR FOREIGN EQUIVALENT IN MECHANICAL ENGINEERING, OR IN A CLOSELY RELATED ENGINEERING FIELD, PLUS WORK EXPERIENCE IN VALIDATION QUALITY ENGINEERING, QA, MANUFACTURING, OR IN A CLOSELY RELATED OCCUPATION.

Special Requirements:

REQUIRED EXPERTISE/KNOWLEDGE OF:

1. Ability to perform Design of Experiment, applied statistics, statistical sampling plans, statistical analysis for process validation and product quality using tools such as Minitab
2. Knowledge of ISO 14644 Cleanroom and associated controlled environments, ISO 14971 Risk Management standards, IEC 62366 Application of Usability Engineering for medical devices, experience with risk management processes including FMEA such as DFMEA and PFMEA.
3. Knowledge of 21 CFR Part 820, EU MDR and other regulatory requirements.
4. Proficiency in validation and verification processes, including IQ/OQ/PQ.
5. Ability to concurrently handle multiple project assignments related to validations on new product development projects.
6. In-depth knowledge of quality assurance principles and practices with experience in ISO 13485 as it applies to responsibilities.
7. Knowledge of data collection and analysis, for reporting of key performance indicators to management.
8. Practical knowledge of manufacturing data systems such as M2M or similar ERP systems.
9. Practical knowledge of Minitab and Visio.

10. Intermediate level scientific technical writing skills for creating and maintaining validation protocols, reports, and SOPs.
11. Understanding of GMP requirements in medical device manufacturing.
12. Industry experience in typical manufacture equipment and processes such as Machining, Heat Treat, Anodize, Passivation, Sterilization, coatings, plastic molding, and sterile packaging.

MUST POSSESS EXPERTISE/ KNOWLEDGE SUFFICIENT TO ADEQUATELY PERFORM THE DUTIES OF THE JOB BEING OFFERED. EXPERTISE/ KNOWLEDGE MAY BE GAINED THROUGH EMPLOYMENT EXPERIENCE OR EDUCATION. SUCH EXPERTISE/ KNOWLEDGE CANNOT BE "QUANTIFIED" BY "TIME."

Up to 5% local travel may be required for the purposes of validation activities.

Salary: $89,090 - $111,300 per year

Pro-Dex, Inc. is an equal opportunity employer.

How to apply: Qualified applicants please send resume to: nicole.mccoy@pro-dex.com. Must reference: LP-25