

Quality Engineer (Reno NV)

The role of a Quality Engineer encompasses all aspects of technical and analytical work required to deliver the objectives of Maruho Medical. Specifically, these include activities related to material inspection (incoming, in-process and final product), first article inspection, design review, validation activities and risk management activities. Specific roles will be assigned by the VP of Quality as required.

1. Job Competencies

Training will be provided where necessary

- Familiarity with quality testing machines and systems
- Thorough knowledge of quality control standards and testing methodologies
- Excellent numerical skills and understanding of data analysis/statistical methods
- Good knowledge of MS Office and databases
- Outstanding communication skills
- Familiar with blueprint interpretation and measuring equipment
- Great attention to detail and a result driven approach
- Excellent organizational
- Knowledge of applicable regulatory standards
- CFR Title 21 Part 820
- ISO 13485:20016
- ISO 14971:2019 Application of risk management to medical devices
- ISO 14644: Cleanrooms and associated controlled environments
- ASTM D4169, Standard Practice for Performance Testing of Shipping Containers and Systems
- AAMI TIR30:2011 (R2016) – A Compendium of Processes, Materials, Test Methods and Acceptance Criteria for Cleaning Reusable Medical Devices
- ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ANSI/AAMI/ISO 11135:2014 Sterilization of Health Care Products – Ethylene Oxide

2. Responsibilities

- Read blueprints and instructions to comprehend the quality expectations for the product and supplies
- Perform inspection with respect to quality standards
- Select output samples and check them using appropriate methods (measuring dimensions, testing functionality, comparing to specifications etc.)
- Use automated systems to perform complex testing procedures
- Maintain records of testing, information, and various metrics such as number of defective products per day etc.

3005 Chastain Meadows Pkwy, Ste. 300, Marietta, GA 30066, USA

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- Monitor the use of equipment to ensure it is safe and well-maintained
- Support the R&D team during Design projects: document review, quality plan, validation, risk management
- Visit supplier and/or perform supplier audit when necessary
- Continually seek process improvements and make recommendations to management
- Prepare and submit reports to the VP of Quality & Regulatory

3. Requirements

- Quick learner, customer focused, accountable, and operates with a sense of urgency
- Demonstrated attention to detail and organization
- Basic PC skills (Microsoft Office: Word, Excel, Outlook)
- Ability to follow written Quality Management System policies, procedures, and work instructions
- Effective oral and written communication skills
- Bachelor's degree
- CQE preferred
- Knowledge of statistical methods and statistical tool (i.e. minitab) preferred

4. Benefits

- Health insurance
- Paid time off
- Dental insurance
- 401(k)
- Vision insurance
- Life insurance
- 401(k) matching
- Flexible spending account