

Quality Engineer Job Description



Job Title:	Quality Engineer
Reports To:	Quality Director
FLSA Status:	Exempt
Department:	Quality

Job Purpose:

The Quality Engineer has the responsibility and authority to provide Quality Engineering representation to management by facilitating product specifications development, product transfer to manufacturing, and process improvements to obtain optimum product reliability, safety, and effectiveness. Coordinates feedback of quality indicators and statistics to management for use in business and product realization decisions.

Duties and Responsibilities

- Develop, perform, direct, or consult in equipment, process and software validations including Installation, Operational, and Process Qualifications.
- Develop test methods and conduct measurement systems analyses, such as gage R&R studies.
- Provide statistical analysis of data in support of quality and manufacturing activities.
- Participate in risk management activities, including process failure mode and effects analysis.
- Investigate, monitor implementation, and report on nonconforming product, corrective and preventive action and continual improvement activities.
- Develop sampling plans and ensure that testing and inspection meet internal and external requirements.
- Participate in product transfer from engineering to production, by reviewing associated documents and developing quality plans.
- Assist in the development of standard operating procedures, work instructions, and forms.
- Review original and revised customer drawings and specifications.
- Minimal travel up to 10%.
- Performs other duties as assigned.

Key Skills and Competencies:

- Knowledge of statistical concepts, methods, and software
- Effective oral and written communications
- Organization
- Planning
- Project Management

Education / Experience:

- BS in Engineering/Biomedical Engineering.

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Employee Signature

Date

Management Signature

Date