

# Quality Engineer

Medical Device/FDA/ISO experience preferred.

## Summary:

Plans and conducts activities concerned with the quality control quality assurance, quality engineering and validation of industrial processes, materials, and products by performing the following duties:

- Essential Duties and Responsibilities: include the following. Other duties may be assigned.
- Assist Engineering in the development of trial and validation protocols and generation of final reports
- Provide assistance and guidance to Engineering and Manufacturing personnel during process development activities.
- Work with Engineering and Project Management during process development and change activities utilizing appropriate Quality tools to ensure robust and fully documented changes and processes
- Evaluates existing processes and leads process improvement activities by ensuring that all processes are completely defined and adequately documented and controlled using appropriate Quality tools, (FMEA, DOE, SPC, Method Development, GRR, etc).
- Determination of Process Capabilities
- Develop problem solving tools and train appropriate personnel
- Assist or Lead the Supplier Improvement process using inputs from the SCAR, NCM and Supplier Audit process
- Assists in external audits by regulatory agencies, certifying bodies or customers
- Lead problem solving teams or be a resource for problem resolution.
- This includes leading or assisting in Root Cause analysis and Corrective Action identification and implementation.
- Able to lead and participate in concurrent teams.
- Conduct, or assist in, customer and supplier visits as required conferring on specific quality issues and/or concerns
- Develops and initiates standards and methods for inspection, testing, and evaluation.
- Plans and conducts the analysis, inspection, design, test, and/or integration to assure the quality of the assigned product or component.

## Education and/or Experience:

- Bachelor's degree (B. A. or B.S.) from four-year College or university; plus 5 years related experience and/or training in a regulated industry preferably medical or pharmaceutical, or equivalent combination of education and experience. Six Sigma Green Belt or Black Belt Certified.

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