

Job Description:

Provide engineering support for activities related to supplier selection and evaluation, material qualification, supplier performance and receiving inspection.

Location: Minnetonka Minnesota

Essential Functions:

- Reviews and approves all supplied product drawings and component quality plans.
Manages development of supplied product inspection procedures and first article requirements
- Provides engineering guidance to receiving inspection including STATISTICAL ANALYSIS, MEASUREMENT TECHNIQUES, GAGE R&R STUDIES, and INSPECTION PROCEDURES\
- Assesses supplier capabilities through direct visits, technical discussions, directed testing and QUALITY SYSTEM AUDITS
- Work with Manufacturing Engineering to assess and address purchased product issues
- Provide design input based on supplier expertise
- Provide manufacturing input based on component and supplier knowledge and supplier capabilities (Polymer Experience strongly preferred)
- Apply sound, systematic problem-solving methodologies in identifying, prioritizing, communicating, and resolving quality issues

Periodic travel required mainly local and domestic for auditing suppliers

Qualifications:

- BS in Engineering
- 5+ years experience
- Previous Supplier Quality engineering experience and demonstrated use of Quality tools and methodologies
- Detailed knowledge of FDA, GMP, and ISO 13485
- Advanced computer skills, including statistical /data analysis and report writing skills
- Medical Device Experience
- ASQ CQE and CQA certification preferred

Please contact:

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