

JOB DESCRIPTION

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| Position Title: Associate Advanced Quality Engineer | EEO Code: 2-3 | Revision: 2.0 |
| Exempt/Non: Exempt Supervisory Responsibilities: No | Department: RA/QA | |
| BASIC FUNCTION | | |
| <ul style="list-style-type: none"> Assist in the development, implementation, and maintaining of plans focused on ensuring quality and compliance of components and finished goods. | | |
| RESPONSIBILITIES | | |
| <ul style="list-style-type: none"> Primary responsibility is to assist in the development of the overall quality approach for new products and line extensions within the new product development and specials process. This includes quality engineering oversight, quality systems implementation including test and inspection plans and product reliability during product development, verification, validation and design transfer while working with Regulatory Affairs Department to ensure compliance to FDA Quality System Regulations and ISO 13485. <ul style="list-style-type: none"> Primarily responsible for: Risk Analysis, Quality Plan, Literature Review, Device Master Record, Quality Training Plan and Technical File. Contributor to: All PPQA Phase 1, 2 and 3 deliverables. Assist in Post Launch Activities or Phase IV of the PPQA process. Participant in new supplier selection, validation, and contract development. Assists vendors in resolving manufacturing and quality issues as required. Responsible for initiating, reviewing, documenting and approving Engineering Change Orders (ECO's) Partners with the operations team to develop and maintain a robust internal and external supply chain. Contribution examples include the performance of supplier audits, risk assessment/mitigation, and coaching. Assists the Advance Engineering in task to mentor the unit quality engineer in the trending and analysis of quality data (e.g. complaints, Tech Support trouble tickets, Pareto charts, scrap, warranty return rate, etc.) and provides guidance to address issues as appropriate. Authors and reviews procedures to ensure GMP and ISO 13485 compliance. Performs internal audits to verify compliance to documented procedures. Participant and/or champion for Corrective Action and Preventative Action (CAPA) process. Assist product quality related projects. Supports the business in addressing and solving quality problems May interact, by telephone or in person, with customers to resolve product issues as part of support escalation model. May train others on quality engineering related topics. Prepares periodic reports on assigned topics to appropriate personnel. May Coach production team members. Other duties as assigned by manager. Has the independence and authority to perform required tasks to ensure all provisions of the quality system are met. | | |

PHYSICAL REQUIREMENTS

- Light work: Exerting up to 20 pounds of force occasionally and/or up to 10 pounds of force frequently and/or a negligible amount of force constantly to move objects.
- Must have the ability to work with and assemble small objects and component parts.
- Ability to operate common office equipment (e.g. calculator, PC, telephone, etc.).
- Must have very good visual acuity and demonstrate fine motor skills.

MENTAL REQUIREMENTS

- Must be able to observe and correct minute inconsistencies (e.g. in the printed word, product appearance, etc.).
- Must be able to generate, follow and explain detailed instructions and inspection procedures.
- Must be able to complete detailed documentation accurately.
- Must be able to analyze and correct complex product and/or process issues using independent judgment.

SKILLS/EXPERIENCE REQUIRED

- Excellent analytical skills.
- Excellent interpersonal communication skills.
- Demonstrated ability to operate small hand tools (e.g. pliers, screwdrivers, hammer, wrenches, etc.), power tools and test/inspection equipment.
- Demonstrated mechanical/electrical or software problem solving skills.
- 4+ years as Quality Engineer or equivalent.
- Experience in developing and working with small group problem solving teams.

EDUCATION/TRAINING REQUIRED

- B.S. in engineering (mechanical, electrical or software preferred).