



POSITION DESCRIPTION

Position Title: Quality Engineer
Issue Date: 11/1/11
Department: Quality Compliance
Status: Consultant
Contact Information: jobs@TearScience.com

PURPOSE OF POSITION: Position and individual will ensure the quality of products using best known technology and company quality systems to assure process stability, capability and continuous improvement while maintaining compliance with ISO 13485, MDD and CFR 820 requirements.

MAJOR DUTIES AND RESPONSIBILITIES:

- Apply engineering knowledge, electrical, mechanical and software skills to meet and facilitate Company's compliance with FDA, MDD, and ISO 13485 quality systems,
- Complete complaint investigations, including adequate root cause analysis; and providing recommendations for corrective & preventive actions,
- Provide support to the R&D, Purchasing, and Supply Chain/Operations during the design transfer to contract manufacturers including IQ/OQ/PQ
- Assists in the manufacturing operation in problem solving with regards to process, equipment and systems.
- Develops and recommends new process equipment and work flows to improve quality, efficiency, and cost effectiveness
- Develop, revise, and complete inspection requirements for receipt of incoming parts and/or final product
- Initiate and investigate NCRMs and participate in Material Review Board
- Implements preventative maintenance and calibration programs for manufacturing equipment and in-process & final test systems.
- Write, update, and review procedures related to manufacturing and product quality
- Train and support personnel in using quality control and manufacturing procedures,
- Assist with supplier selection and second sourcing



- Work with the Quality Team to continually improve quality and quality systems in manufacturing, and ensure compliance with FDA, MDD, and ISO 13485
- Manage, plan, schedule, and implement in an aggressive manner consistent with company objectives and customer needs a quality inspection process to facilitate the meeting of Company's supply chain goals and objectives.
- Support company goals and objectives, policies and procedures to achieve and meet FDA, ISO and International MOH regulations.

DESIRED QUALIFICATIONS & EXPERTISE:

- Working knowledge of electro-mechanical devices, which include software and a computer.
- Ability to utilize root cause analysis for complaint investigations
- Developed corrective actions to ensure continuous improvement on all aspects of their manufactured and sourced products
- Demonstrated working knowledge of statistical principals, successful experience with controlling manufacturing processes using industry standard quality assurance techniques
- Demonstrated ability to read engineering drawings, electrical schematics, and work with the design team to insure they have robust designs that are manufacturable and inspectable
- Experience making improvements and/or design modifications to solve a problem before it makes it into manufacturing
- Ability to work with internal and external TearScience team members and to work independently through self-motivation while maintaining a professional and credible image with customers, consultants, vendors and co-workers.
- Position and individual must have hands on experience with medical devices dealing with risk management, verification and validation of Class II medical devices.
- Good organization and communication skills and able to prioritize workload with ability to negotiate with customers while exhibiting critical problem solving skills.
- Venture backed company or small company experience.

EDUCATION & EXPERIENCE REQUIREMENTS: BS Engineering or equivalent required with a minimum of four years experience. Ideally, minimum of 2 years of experience in the Class II medical device industry with hands on experience in ISO, MDD, and FDA quality systems.