



IC Biomedical Job Description

Quality Engineer

IC Biomedical, LLC manufactures cryogenic storage and transport equipment for life sciences, healthcare, and animal husbandry markets.

Job Summary

The quality engineer is responsible for ensuring manufacturing and QMS processes are performed correctly using the right tools, materials, and processes. An important part of the job involves working with internal teams to determine the company's quality expectations and develop metrics/processes to constantly determine if expectations are being met. The QE will document problems and play a lead role in determining root cause and work with other departments to implement solutions. The QE will gather and report process statistical information to identify areas requiring improvement. The QE is responsible for monitoring, inspecting, and proposing measures to correct or improve final products and processes to meet established quality standards. The QE will assist in quality assurance audits to ensure product and regulatory requirements are being met. The QE should have experience in trouble shooting processes and systems to ensure reliability and consistent results.

Essential Duties & Responsibilities to Include:

- Troubleshooting equipment, processes, and products to determine corrective actions and improvements.
- Developing quality systems to monitor and control processes.
- Work with managers and supervisors to implement quality measures
- Monitor and report on process performance metrics
- Support action item implementation
- Play a lead role in monitoring key processes and working with other departments to identify issues and corrective actions.
- Assisting in audits based on ISO 13485:2016 requirements and other regulatory compliance requirements
- Determining achievable quality objectives for all manufacturing processes.
- Set detailed guidelines on in-process inspections and testing to be performed.
- Continuously monitor Quality Management System (QMS) and implement improvements.
- Perform first article and incoming inspections
- Review and approve Engineering Change Orders and quality documentation for accuracy and compliance
- Work with internal teams to increase customer satisfaction by improving the quality of the products
- Determines quality improvement parameters by identifying statistical methods relevant to manufacturing processes

- Experience and capability to manage a calibration system
- Identifying and resolving workflow and production issues
- Ensure current product quality specifications fulfill customer requirements and expectations

Qualifications:

- Detail oriented, able to multitask and meet deadlines
- Self-motivated, able to work in a team and independently
- Hands-on experience with Quality Management Systems (QMS) and testing methodologies
- In-depth understanding of technical documentation
- Familiarity with statistical analysis
- Proficient in computer technology and systems
- Great attention to detail and problem-solving abilities
- Excellent analytical skills
- Self-starter
- Strong experience with Microsoft Office products (especially excel) and are comfortable learning new technology
- Ability to make informed decisions that are in the best interest of the organization
- Must be able to resolve issues, to identify the cause for accurate resolution and to prevent future occurrence, and know when to escalate
- Communication and Relationships: Strong interpersonal skills to work with directly with team members, suppliers, and internal customers. Good verbal and written communication skills are required.
- Flexibility: Ability to handle multiple tasks simultaneously, work in a fast-paced environment, responsive in reacting to a changing and dynamic environment

Education and Experience

- Previous work experience as a Quality Engineer or similar role
- Experience with ISO 13485:2016 or other QMS standard
- Experience with Root Cause Corrective Actions (RCCA) and failure analysis
- ASQ Certified Quality Engineer a plus
- Bachelor's degree from an accredited course of study in engineering or computer science preferred

Safety

- Follow all PPE and safety rules
- Promote a safe and healthy work environment
- Ensure compliance with all regulatory and company policies and procedures

Location:

Cartersville, GA

IC Biomedical is an equal employment employer