SENIOR QUALITY ENGINEER / SUPPLY CHAIN

Ann Arbor, MI

MC3 Cardiopulmonary is focused on fast becoming a leading medical device developer and manufacturer. With deep roots in patient physiology, hemodynamics, technology, and caregiver needs, the Company is well positioned to deliver intelligent solutions that address critical unmet needs.

This position is a key technical role responsible for the development, implementation, improvement and continuous reinforcement of established Quality Assurance fundamental practices. The role involves hands-on work with MC3 and our suppliers in the areas of design, design transfer, manufacturing, distribution, and/or service.

Position Responsibilities:

- Ensures quality and regulatory compliance in accordance with documented procedures for all aspects of functional responsibility.
- Supports continuous product and process improvement through detailed failure analysis for non-conformances, and investigates, develops and implements effective and compliant solutions for product or process corrections, retrospective and remediation action plans, and for corrective and preventive actions (CAPA Program). Able to lead, develop, communicate & implement essential containment or corrective actions effectively under potentially stressful situations.
- Utilizes risk management tools and aids for use by the organization in accordance with documented procedures, including but not limited to PFMEA, DFMEA, Fault Tree Analysis, Failure Mode Analysis, etc.
- Supports design mitigation and process mitigation plans and strategies that are designed to mitigate the risks identified through the Risk Management process.
- Develops process improvement plans using a variety of Quality and Continuous Process Improvement tools, including but not limited to Six Sigma, Lean Manufacturing, 5S, SPC, engineering studies, DOE, Gauge R&R, etc.
- Performs external audits and participates in internal audits.
- Performs a broad variety of tasks in support of product and process design as assigned by the departmental manager.

Experience and Qualifications:

- Bachelors of Science Degree in Engineering
- 4 years' experience, at least one year in life science regulated industry, experience in manufacturing of sterile medical products a plus.
- Exceptional analytical, problem solving & root-cause analysis skills.
- Strong technical aptitude (i.e. able to read & comprehend technical documentation & execute procedures), medical device quality system experience & demonstrated experience interfacing with regulatory bodies and FDA.
- Excellent communication skills (written and oral). Team player with demonstrated collaboration, negotiation & conflict resolution skills.
- Ability to multi-task and handle tasks with competing priorities effectively.

- Demonstrated understanding of statistics & experience with continuous quality / process improvement tools: (As defined by the local site, e.g. SPC, Lean SS, 5S)
- Demonstrated experience and proficiency with MS Office word processing, spreadsheet, presentation, and database applications.

Travel Required:

- Valid US Driver's License
- Travel expected both domestic and international – up to 30%

Let us know you want to join our team by submitting your resume and letter of interest to careers@mc3corp.com with "Senior Quality Engineer Supply Chain" in the subject line.