



SENIOR MANUFACTURING ENGINEER

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.

The Senior Manufacturing Engineer plans, directs installation, and oversees manufacturing processes and equipment in a medical products environment.

Position Responsibilities:

- Develop new and/or improved manufacturing methods utilizing knowledge of product design, fabrication processes, tooling and equipment capabilities, assembly methods and quality requirements
- Assures process efficiency by analyzing and planning workflow, space requirements, labor efficiency, and layout of equipment
- Develops operations and manufacturing SOP's and work instructions, and trains manufacturing associates on these procedures
- Specifies and purchases equipment and machinery. Partners with equipment and machinery suppliers to determine specifications, capability, and suitability for purpose.
- Manages the installation of equipment
- Develops and manages preventative maintenance and calibration requirements for facilities and equipment as required
- Responsible to writing Master Validation Plans, Process Risk Assessment (PFMEA), and Test Method Validations for new and existing product implementation or changes
- Writes and executes IQ, OQ, and PQ process validations. Partners with Quality on the appropriateness of validation protocols.
- Integral member of product development teams to provide manufacturing expertise and assure design for manufacturability
- Assists in transfer of sub-contracting of processes to outside processors
- Leads continuous improvement and problem solving teams. Uses advanced methods and tools, including such methods as Six-Sigma and LEAN.
- Stays current on relevant safety and environmental codes and regulations, and assures compliance to these codes

Experience and Qualifications:

- B.S. University or college degree in a technical discipline
- 5 to 10 years' manufacturing engineering experience in the disposable medical device industry or equivalent regulated industry



- Proficient at writing and executing Master Validation Plans, Process Risk Assessment (PFMEA), Test Method Validations, and Process IQ/OQ/PQ validations.
- Experience in selection and/or design of manufacturing equipment, tools and fixtures.
- Experience in designing effective work flow to meet production and quality requirements
- Ability to work effectively with teams and individuals including production personnel
- Skill in creating/reading technical drawings and specifications
- Excellent technical problem solving skills
- Excellent written and oral communication skills

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