5991 Chester Ave, Suite 211
Jacksonville, FL 32217
Phone: 1 (888) 767-8233
Fax: 1 (904) 240-4068

Mark V.
Manufacturing Engineer

PROFESSIONAL SUMMARY

Manufacturing Engineer in the Medical Device Industry, possess extensive experience in supporting production, processes, materials, and equipment systems. Working experience in maintaining manufacturing documentation, including work instructions, SOPs, change control documentation, NCRs, and CAPAs. Proficient in establishing procedures for documentation for Master Validation Plans, PFMEA, and Validation activities (IQ, OQ, PQ). Skilled at performing audits and using continuous Improvement tools, including Six Sigma, Lean Manufacturing, SPC, DOE, and Gage R&R. Exp. Involve in developing and delivering new manufacturing process capabilities studies and enhancing NPD. Extensive experience in compliance with 21 CFR 820, ISO 13485, ISO 14971, and GMP and regulatory requirements, implementing validation protocols, inspection plans, and regulatory compliance operating procedures to FDA requirements.

EDUCATION:

Texas Tech University, Lubbock, Texas
Master of Science in Industrial Engineering

Texas Tech University, Lubbock, Texas
Bachelor of Engineering in Mechanical Engineering

EXPERIENCE

REDACTED **2023- Present**

Manufacturing Engineer

- Responsible for implementing process equipment maintenance according to current Good Manufacturing Practices (cGMPs) and following Standard Operating Procedures (SOPs).
- Maintained manufacturing documentation including Manufacturing work instructions, SOPs, change control documentation, NCRs, and CAPAs
- Conducted process validations, ensuring compliance with regulatory requirements and industry standards in injection molding.
- Developed and delivered new manufacturing process capabilities process selection, characterization and qualification using design of experiment methodology.
- Worked with new product development teams and product support, including process capability studies, process development, Six Sigma, and Value Improvement projects, report preparation, and process documentation.
- Analyzed instrument manufacturing line from a risk perspective (PFMEA) to incorporate and validate critical tests used in manufacturing.
- Supported product and process improvement using a variety of Quality and Continuous Improvement tools, Six Sigma, Lean Manufacturing, SPC, DOE, Gauge R&R.
- Performed detailed time studies, motion studies, capability studies and spending significant time observing the line, equipment, and product flow.
- Maintained the CAPA procedure, initiated investigation of non-conformances (NCR) through root cause analysis, and evaluated the effectiveness of the CAPA process.
- Developed and implemented master validation plans, validation protocols, inspection plans and regulatory compliance operating procedures to meet FDA and ISO requirements.

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- Performed troubleshooting on new and existing products/process problems related to design, material, and processes.
- Performed manufacturing concepts like Value Stream Mapping, 5S, and Visual Workplace to improve quality, labor efficiency, and throughput.

Johnson & Johnson **2020- 2023**
Manufacturing Engineer

- Designed and optimized manufacturing processes for the production of component parts and sub-assemblies, ensuring efficiency, quality, and regulatory compliance.
- Conducted regular audits of molding processes to identify areas for improvement and ensure compliance with quality and safety standards.
- Designed and modified process models to ensure compliance with FDA, ISO 13485, and other relevant medical device quality standards.
- Implemented time calculations for various manufacturing processes, accurately estimating production cycle times and resource requirements.
- Collaborated with cross-functional teams, integrating CAD designs into the overall manufacturing process, ensuring design intent is maintained.
- Developed documentation and standard operating procedures (SOPs) for the assembly and operation of electromechanical devices.
- Conducted design of experiments (DOE) using Minitab to identify key factors influencing product performance and manufacturing efficiency.
- Implemented changes to streamline production flows, reducing lead times and improving overall operational efficiency.
- Implemented Lean Manufacturing principles to systematically eliminate waste and improve overall production efficiency.
- Used visual management techniques to quickly identify and address issues, promoting a culture of transparency on the shop floor.
- Ensured failure investigations for root cause identification for high complaint rate failure modes following DMAIC methodology
- Provided engineering support in the troubleshooting of process or product issues, including root cause failure analysis of discrepant materials and assemblies, including CAPA activities
- Performed root cause analysis of non-conforming materials and determine corrective actions to resolve issues with non-conforming parts.
- Performed Design for Manufacturing and Assembly (DFMA) analysis for assembly components.

Argon Medical Devices **2017 - 2020**
Manufacturing Engineer

- Maintained manufacturing documentation, including work instructions, SOPs, change control documents, NCRs, and CAPAs.
- reviewed Process Qualifications, Test Method Validations, Gage R&Rs, Process Capability studies, Design of Experiment (DOE).
- Supported QMS compliance by performing acceptance activities, CAPAs, NCRs, QRB, process improvements, and operator training.
- Worked on identifying opportunities for process improvement, led continuous improvement initiatives, support problem solving production issues, and report on quality trends.
- Utilized tools associated with risk management (e.g. PFMEA) to identify potential risks and the associated corrective actions.

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- Participated in Failure Mode and Effect Analysis (FMEA) and Operational Quality Risk Assessment processes to help reduce process deviations
- Reviewed and approved Process Validation Protocols from manufacturers to ensure that the process meets FDA requirements, complies with GMPs, and company policies and procedures.
- Performed statistical analysis of process data, DOE, process mapping, IQ/OQ/PQ, control plans, and summary reports via Minitab.
- Provided technical support for production issues, including part and assembled product quality dispositions, root cause analysis, resolution planning, validation, and implementation under NCMR or CAPA.
- Wrote and maintain SOPs for incoming inspection, in-line testing, and assembly operations.
- Conducted manufacturing processes, tooling, and fixtures to meet daily production schedules.

ADDITIONAL WORK EXPERIENCE AND REFERENCES AVAILABLE UPON REQUEST