**SR – Process Engineer**

**Summary:**

Experienced process engineer with a track record in manufacturing support, process improvements, and quality systems excellence. Adept at investigating customer complaints, implementing CAPA projects, Non-conformance and driving cost improvement. Skilled in developing standard operating (SOP) procedures and providing field troubleshooting support. Proficient in commissioning and qualification documentation, statistical data analysis tools, and root cause analysis. Knowledgeable in GMPs, FDA guidelines, and ISO standards. Expertise in process mapping, sterilization processes, equipment qualification, continuous improvement and driving positive change through value stream and facilitating in manufacturing environments. Familiar with MS Office Suite like Word, Excel, PowerPoint.

**Work Experience:**

**XXXXXXXXXXXXXXX**

**Process Engineer**

* Responsible for providing day-to-day support in the manufacturing area, working on sterilization process, non-conformance, CAPA activities, implementing process improvements and driving cost improvement projects in manufacturing processes.
* Responsible for Customer Complaint Investigations, CAPA projects, Cost Reduction and Continuous Improvement projects, Quality Systems Excellence among other projects.
* Developed and documented standard operating procedures (SOPs) for metal finishing operations, ensuring consistent and efficient processes across the manufacturing facility.
* Provided support to manufacturing operations through field troubleshooting, process monitoring, and development of process improvements.
* Implemented and reviewed Commissioning and Qualification documentation such as project plans, protocols, and reports.
* Performed investigation corrective action (NCMR & CAPA), mechanical drawing, six sigma, design of experiments, creating SOP's, documentation as per GDP requirements.
* Investigated manufacturing yield and product nonconformance issues, determine root causes, and implement corrective and preventative actions.
* Supported Value Stream, Cell Implementation for continuous improvement and positive change.
* Provided support on GMPs, device testing and validation, industry and regulatory guidance documents, FDA guidelines, and ISO standards.
* Used statistical data analysis tools like Minitab for capability analysis. Used problem solving tools like process map, Pareto chart, 5 whys, and cause and effect matrix for root cause analysis.
* Performed statistical analysis of process data, including Design of Experiments (DOE), process mapping, IQ/OQ/PQ, sterilization process, control plans, and summary reports, using Minitab.
* Performed review and approval of Manufacturing, Quality and Facilities deviations, GMP, Audits and corrective actions (CAPAs).
* Reviewed and approved process and product validation protocols and Validation reports, equipment qualification, change controls).
* Prepared the Technology Transfer Documents like Process flow charts (PFC), Equipment suitability report, Process flow diagram (PFD), P&ID and equipment compatibility.
* Applied statistical process control (SPC) methods for analyzing data to evaluate the current process and process changes for the development of new products.

**XXXXXXXXXXXX**

**Process Engineer**

* Executed process validation protocols for new metal finishing equipment, ensuring compliance with regulatory requirements and industry standards.
* Analyzed and resolved technical and operational problems, working with the value stream to support troubleshooting of chemical production issues.
* Documented equipment requirements, specifications, design, and operation in compliance with Good Manufacturing Processes.
* Supported the evaluation, analysis, and implementation of projects driving Quality, Delivery, and Cost Improvements to manufacturing processes
* Supported investigation on part nonconformities, customer complaints & Corrective & Prevention Action (CAPA).
* Performed Quality System development and improvement with respect to GMP systems and development team compliance to ISO and FDA regulations.
* Involved in updating Failure Mode Effects Analysis (FMEA) and statistical data analysis to improve robustness of process (Minitab, Gage R&R).
* Worked with cross-functional teams through system improvement projects such as the improvement of process validation documents including IQ/OQ/PQ, SOPs, and process information documents.
* Worked with NCR’s team to initiate, document Non-Conformances, routing for approvals.
* Executed IQ/OQ/PQ protocols and completed reports for equipment, process utility, test, and software validations and revalidations.
* Planned and monitored lean manufacture, issuing the roots of cause analysis and process improvement. Established process methods to meet performance and quality requirements.
* Identified and implemented continuous improvements using Six Sigma, lean, process improvements, new fixturing, and improved fixtures.

**Education:**