**Manufacturing Process EngineerSummary:**

* Proven track record in optimising manufacturing processes, ensuring equipment reliability, and leading Lean and Six Sigma initiatives for continuous improvement.
* Strong communicator with exceptional technical writing skills, adept at implementing critical quality parameters, process attributes, and conducting Quality Risk Assessment for Automation and Equipment Systems (QRAES).
* Skilled in User Requirements Specification (URS), validation protocols, Commissioning and Qualification Plan (CQP), calibration, and proficiency with GMP process equipment, automation infrastructure including Delta V and Rockwell systems, and various process improvement methodologies.

**Experience:**

**Manufacturing process Engineer ABC Medical Devices, Cityville, CA June 2022 – Present**

* Led comprehensive process optimization initiatives, ensuring strict compliance with cGMP standards and regulatory requirements.
* Managed critical capital projects and equipment reliability programs, aligning strategies with business objectives to enhance operational efficiency and productivity.
* Developed and executed validation protocols, adhering to regulatory standards and ensuring robust qualification of manufacturing equipment and processes.
* Acted as a pivotal liaison between engineering and quality assurance teams during project execution phases, facilitating seamless integration and adherence to quality standards.
* Implemented risk-based approaches for process validation and verification, minimising project costs while maintaining high-quality standards.
* Conducted Root Cause Analysis (RCA) and effectively managed Corrective and Preventive Actions (CAPA) to resolve and prevent manufacturing issues, ensuring continuous process improvement.
* Provided expert technical support and guidance to cross-functional manufacturing and maintenance teams, fostering a collaborative environment focused on achieving operational excellence.
* Led Lean and Six Sigma initiatives, resulting in significant process efficiencies and cost savings across manufacturing operations.
* Successfully participated in regulatory inspections, defending equipment validations and ensuring compliance with stringent regulatory requirements.
* Developed and maintained comprehensive process control plans and documentation, ensuring transparency, traceability, and compliance with regulatory guidelines.

**Manufacturing process Engineer Boston Medical Devices, Cityville, CA June 2020 – May 2022**

* Supported the optimization of manufacturing processes for pharmaceutical production, focusing on enhancing product quality and process efficiency.
* Conducted rigorous process validation activities (IQ, OQ, PQ) to ensure compliance with regulatory standards and validation protocols.
* Utilised Failure Modes and Effects Analysis (FMEA) to identify and mitigate potential risks in manufacturing processes, enhancing process reliability and product safety.
* Developed and implemented robust process control plans, leveraging Statistical Process Control (SPC) methodologies to monitor and improve process performance continually.
* Applied Lean and Six Sigma methodologies to streamline operations, resulting in significant improvements in operational efficiency and reduction in production costs.
* Managed documentation for process validation and equipment calibration, ensuring accuracy and compliance with regulatory requirements.
* Conducted Root Cause Analysis (RCA) investigations and led CAPA initiatives, addressing non-conformances promptly and preventing recurrence.
* Provided oversight for contract resources and verified deliverables, ensuring alignment with project timelines and quality objectives.
* Actively participated in cross-functional teams to drive process improvements and operational excellence initiatives, fostering a culture of continuous improvement.
* Supported internal audits and maintained compliance with Good Manufacturing Practices (GMP) standards, ensuring adherence to quality and regulatory requirements.

**Manufacturing process Engineer ABC Medical Devices, Cityville, CA June 2018 – May 2020**

* Collaborated in the development and implementation of innovative manufacturing process improvements, focusing on enhancing operational efficiency and product quality.
* Conducted comprehensive statistical analysis and utilised Statistical Process Control (SPC) techniques to monitor and optimise process performance, ensuring consistency and reliability.
* Supported the creation of Standard Operating Procedures (SOPs) and facilitated training programs for manufacturing staff, promoting adherence to best practices and regulatory requirements.
* Conducted equipment qualification and validation activities, ensuring alignment with stringent regulatory standards and industry best practices.
* Implemented robust risk management principles to identify and mitigate potential operational risks, enhancing overall process safety and reliability.
* Actively participated in internal audits, ensuring compliance with GMP standards and contributing to continuous improvement efforts across manufacturing operations.
* Managed the creation and maintenance of manufacturing documentation and records, ensuring accuracy, accessibility, and compliance with regulatory requirements.
* Conducted Gage Repeatability and Reproducibility (Gage R&R) studies to validate measurement systems, ensuring precision and reliability in quality inspections.
* Collaborated cross-functionally to resolve complex manufacturing issues, applying analytical thinking and problem-solving skills to drive sustainable process improvements.
* Supported and contributed to ongoing initiatives focused on enhancing process efficiency, quality, and operational excellence within the organisation.