**Process Engineer**

**Summary:**

* Highly skilled in process development, validation, and technology transfer for pharmaceutical manufacturing.
* Extensive experience with cGMP compliance and various drug product technologies.
* Proficient in conducting characterization studies and analysing experimental data.
* Strong background in authoring technical documents and reports.
* Demonstrated ability to work on multiple projects and thrive in dynamic environments.

**Experience:**

**Process Engineer***Innovative PharmaTech  
August 2015 - Present*

* Led process development initiatives to optimise drug product manufacturing technologies, including freeze/thaw, formulation, and lyophilization.
* Conducted comprehensive process validation activities, including IQ, OQ, and PQ, ensuring compliance with cGMP and regulatory requirements.
* Performed Failure Modes and Effects Analysis (FMEA) to identify potential risks in manufacturing processes and implemented mitigation strategies to enhance process reliability.
* Developed and implemented process control plans, using SPC methods to monitor and control process performance, ensuring consistent product quality.
* Executed characterization studies at lab and production scales, generating technical data packages and ensuring reproducibility and reliability of results.
* Applied Lean and Six Sigma methodologies to streamline processes, reduce waste, and improve operational efficiency.
* Authored and reviewed technical documents, such as protocols, technical reports, and standard operating procedures, ensuring thorough documentation and compliance.
* Conducted statistical analysis using software like Minitab and JMP to support process optimization and decision-making.
* Liaised with various drug product teams, ensuring successful technology transfer and compliance with regulatory standards.
* Supported internal audits and regulatory inspections, maintaining a strong compliance record and ensuring readiness for regulatory reviews.

**Process Engineer***BioPharm Solutions  
June 2012 - July 2015*

* Supported process development and optimization efforts for drug product manufacturing, focusing on formulation, mixing, and filtration techniques.
* Executed process validation activities, including IQ, OQ, and PQ, ensuring adherence to cGMP standards and regulatory requirements.
* Performed FMEA to identify and mitigate risks in manufacturing processes, enhancing overall process robustness and reliability.
* Developed process control plans and utilised SPC methods to monitor and control manufacturing processes, ensuring stable and high-quality production.
* Conducted characterization studies at lab and production scales, analysing data and ensuring reproducibility of results.
* Applied Lean and Six Sigma methodologies to improve operational efficiency and reduce waste.
* Managed documentation for process validation and equipment calibration, ensuring accuracy and regulatory compliance.
* Provided technical support and guidance to manufacturing teams, fostering a collaborative environment and promoting knowledge sharing.
* Authored and reviewed technical documents, ensuring thorough documentation and compliance with regulatory standards.
* Supported internal audits and regulatory inspections, maintaining compliance with GMP standards and ensuring readiness for audits.

**Process Engineer***PharmaTech Innovations  
August 2008 - May 2012*

* Assisted in the development and implementation of manufacturing process improvements, focusing on enhancing process efficiency and product quality.
* Conducted statistical analysis and utilised SPC to monitor and control manufacturing processes, ensuring process stability and product consistency.
* Supported the creation of SOPs and training programs for manufacturing staff, promoting adherence to standardised procedures and regulatory compliance.
* Conducted equipment qualification and validation to meet industry standards and regulatory requirements, ensuring reliable performance.
* Implemented risk management principles to identify and mitigate potential risks in manufacturing operations, enhancing process reliability and safety.
* Participated in internal audits, ensuring compliance with GMP and cGMP standards, and supporting audit preparations and responses.
* Managed manufacturing documentation and records, ensuring accuracy and traceability to support regulatory compliance and audit readiness.
* Conducted Gage R&R studies to ensure measurement system reliability and accuracy.
* Collaborated with cross-functional teams to address and resolve manufacturing issues, fostering a collaborative environment to achieve shared goals.
* Supported continuous improvement initiatives, contributing to significant process improvements and operational advancements.