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Process Engineer

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Company: Technical Source

Location: United States

Category: other-general

Our client is looking for an experienced process engineer to join their Fill/Finish team. This person should have at least 5 years of experience as a process engineer at a pharmaceutical manufacturing plant. This role includes but is not limited to mechanical troubleshooting, supporting identification and implementation of process improvements, system design, capital project support, and investigation support. Individual ensures all Process Engineering documentation deliverables are generated, and is expected to develop new processes and/or optimize existing ones. Responsibilities: Acts as the SME for critical process operations within filling and packaging operations. Must have project management skills, knowledge and application experience of technical design reviews, commissioning, and validation for pharmaceutical processes. Individuals will be expected to work routinely with cross functional groups throughout the site for process improvements and implementation. S/he must have a solid understanding and knowledge of pharma regulations and cGMP principals and demonstrated ability to apply knowledge to process improvements and changes. Will be responsible for interfacing with auditors and presenting on-site processes. Leads FAT (factory acceptance testing) and ensures protocol execution is per plan, supports installation, operational, and performance qualification activities. Direct the work of other process engineers and contract engineering resources, to include performance evaluations for Pfizer direct reports. They will be expected to establish methods for ongoing monitoring/trending of process/mechanical issues and will be responsible for review and approval of site documents to include calibration reports, batch records, SOP's, change control, and design specs.

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