

**Job Title:** Project Engineer

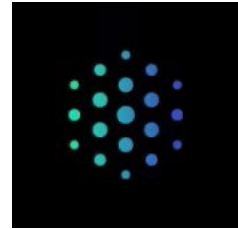
**Location:** US-NJ-Lakewood

**Overview:**

The Project Engineer is responsible for managing construction and engineering projects in a cGMP environment through planning, organizing, and controlling all elements of the project. Have the ability and competency to oversee all facility and utility upgrade projects, inclusive but not limited to area renovation, new cGMP manufacturing suites, and purchase of new manufacturing equipment. Apply engineering principles to support operational initiatives such as equipment reliability enhancement, environmental sustainability, project execution standardization and continuous improvement. Ability to work in a fast-paced environment and the competence to concurrently handle multiple projects and operational initiatives. This position is exempt from overtime.

**Responsibilities:**

- Manage small, medium, and large projects from requirement specifications & design to implementation and validation phases
- Drive and ensure compliance with all federal and state regulations, including OSHA, DEP, EPA, FDA.
- Create detailed project plans and schedules using MS Project to drive successful project outcome, while driving accountability.
- Prepare project support documentation, including: project scopes, presentation of conceptual designs, capital requests, purchase orders, project plans and schedules, user/functional specifications, design specifications, piping and instrumentation diagrams, process flow diagrams, start-up and equipment operational procedures and commissioning.
- Control project cost by ensuring robust contractor agreements are in place, prior to commencing any work, and by closely monitoring and approving capital expenditures.
- Prepare and review contractor bids, interviews and vendor selection.
- Ensure appropriate communication to all project stakeholders through meetings, project reports, and other forms of communication.
- Design and specify HVAC systems and other utility solutions (WFI Water, Compressed Air, Vacuum, Clean Steam, Nitrogen, etc.) in support of manufacturing, packaging and laboratory spaces.
- Knowledge of cGMP manufacturing space construction in compliance



- with ISO 14644 Cleanroom standards.
- Knowledge of Building Management Systems and Computerized Maintenance Management Systems.
- Perform design review for all construction related designs: mechanical, electrical and plumbing.
- Assist in the design review, factory acceptance, site acceptance, installation of equipment, as well as equipment qualification
- Evaluate equipment performance and provide improvement recommendation for equipment optimization, while ensure safe operation.
- Support compliance activities, such as change control, deviation management and CAPA resolution
- Assist in investigations of facility equipment, utility systems, and control anomalies as well as safety incidents.
- Write and modify procedures for the proper operation of new and/or existing equipment.
- Assist in equipment transition from validation to commercial/developmental line use
- Propose and implement operational efficiency improvements for facility and utility systems.
- Assist with training of operations and maintenance personnel, as needed.
- Perform other duties and responsibilities as assigned.

**Qualifications:**

B.S. degree in Mechanical, Electrical Engineering is required. 3 to 7 years of relevant experience in the pharmaceutical industry and PMP certification is a plus.

Must possess:

- A thorough knowledge of construction in a cGMP environment, HVAC design and controls requirements.
- Advanced knowledge of engineering documentation required for cGMP processing and substantial knowledge of cleanroom design and operation.
- Extensive knowledge of project management, utilizing PMO standards.