

The Process Engineer is a professional who understands lean manufacturing concepts, can implement continuous improvement, and support production through analysis of production metrics to provide ways to simplify process and optimize results, and exceed targets and timetables. The Process Engineer must be a self starter, task oriented, like projects, maintain strong work ethic, offer more than is asked for, and have the potential to see the big picture.

Primary Responsibilities:

Knowledge and experience working under GMPs and validation requirements.

- Perform the design and implementation of chemical processes, instrumentation and equipment.
- Provide process and clean utilities engineering support on a daily basis.
- Review and provide recommendations on design drawings.
- Provide key input into the validation of process equipment and associated utilities.
- Generate and/or review controlled documents to support start-up, operation, validation or maintenance of equipment and systems.
- Perform equipment systems studies.
- Research/evaluate process equipment components.
- Review/modify equipment operations as a result of troubleshooting.
- Establish operating equipment specifications and improve manufacturing techniques, when relevant.

Basic Accountabilities:

Responsibilities include, but are not limited to, the following:

- Plan, develop, document and train all lean initiatives, implementing best practices in each assigned plant project.
- Create a system to identify trends and patterns in historic production data to assist in the establishment of new standards and manufacturing methods.
- Use statistical analysis to understand capability indices of the components of the production process.
- Engineer work processes, including line layout, process flow, equipment selection, equipment optimization and equipment modification.

Responsibilities Specific to Skill Area:

- Engineering:
 - Client consultation regarding technical approaches to projects
 - P&IDs and Functional and Detailed Design Specifications review and development
 - Clean water systems, CIP, SIP, and process equipment
 - Engineering project management
- Controls:
 - The design, programming, testing and start-up of PLCs, SCADA and HMI interfaces, and integrated systems
 - DCS and Delta V

- Validation:
 - Installation, Operational and Performance Qualification Validation protocols development
 - Approved protocols execution
 - Coordination with other functional departments
 - Qualification data analysis with respect to pre-defined acceptance criteria
 - Protocol discrepancies or deviations generation and resolution
 - Final protocol reports development
 - Internal quality systems and procedures development and maintenance

Requirements:

- A B.S. or M.S. degree in Engineering (Chemical or Mechanical preferred)
- 5-7+ years in equipment, process or clean utility systems experience is required.
- Must comply with cGMP requirements (gowning, documentation, procedures) and have the ability to generate engineering drawings and specifications.
- Must possess a good understanding of clean room or classified area design/requirements.
- Individual will be expected to use creativity and innovation to address urgent and/or complex problems and propose solutions and have the ability to work autonomously on assignments and projects.
- Strong verbal and written communication skills; excellent organizational and time utilization skills.
- Strong computer knowledge including Microsoft Office products and AutoCAD or equivalent
- Proficient knowledge of biopharmaceutical manufacturing, design or construction is required.
- Proficient knowledge of biopharmaceutical manufacturing, process equipment and supporting utility systems, especially related to sanitary and sterile operations, is essential.
- Environmental compliance experience
- Relate to people at all levels of the organization, including diverse cultures
- A strong willingness to travel