

The Manufacturing Engineer is responsible for providing engineering expertise in the areas of new product development, process development and improvement, equipment and sustaining engineering, manufacturing technologies, and project support to assure the production of World Class products.

Specific Roles and Responsibilities include the following:

- Integrity of Manufacturing Instructions (MI's)
- Approve Manufacturing Routings and BOM's, execute changes as required
- Equipment status, operating condition, and operating procedures (EIN's)
- Work station layout, equipment required, access to tools, storage of tools and equipment
- Material and process flow through the work areas
- Process improvement activities
- Process troubleshooting
- Capacity Analysis
- Cross-functional communication with individuals and departments that have a stake in the manufacturing operations
- Write validation protocols
- Write and Execute process and equipment validations
- Develop operator training protocols and assist in operator training
- Develop and Implement MFG documentation for new products and processes
- Communication with area manager, lead, supervisor, QE, and product improvement group
- Monitoring of equipment set-ups, documentation, and operating parameters
- Process yields and scrap
- New Equipment acquisition

ESSENTIAL FUNCTIONS:

New Product Development

- Develop manufacturing strategies to support the transfer of products from R&D to production and ensure product specifications are consistent with standard raw materials and manufacturing processes.

Equipment Engineering

- Generate equipment specifications defining machine performance criteria that are quantifiable by SPC and FEMA analysis. Develop new equipment strategies and generate documentation to support procurement of capital equipment. Develop manufacturing control plans and metrics that verify machine outputs are compliant with QSR standards. Support machine build activity through regular design reviews and milestones. Install and validate existing and new equipment, generate equipment operating instructions and conduct operator and maintenance training.

Sustaining Engineering & Process Improvement

- Apply engineering techniques to sustain and maximize current manufacturing efficiencies. Areas include: wet chemistry processing and filling, automated and manual assembly. Identify and implement new technologies and continuous improvement to optimize manufacturing process output. Develop and maintain Manufacturing Instructions, SPC, Routings and Bill of Materials. Perform analysis, testing and qualification as required to support raw material and part configuration changes. Identify process control points and implement appropriate process control parameters.

Project Support

- Manage and / or provide engineering guidance for cross-functional project teams functioning at either the team leader or team member capacity. Generate project plans and timelines using Microsoft® Project. Organize and manage team meetings, generate agendas and write meeting minutes. Responsible for meeting all team objectives.

Documentation

- Generate documentation for production operations including manufacturing and equipment instructions, validation protocols, design control, pFMEA, and control plans. Maintain and generate new item information and routings per ERP requirements. Submit documents and create ECO's for any new and existing product and processes per Document Control guidelines.
- Carries out duties in compliance with established policies

INTERACTIONS:

- The Manufacturing Engineer is responsible for performing cross-functional tasks that require the individual to interact with members from all departments at various levels within the organization. Primary customers include Scientists, Production Managers, and Marketing Representatives, as well as the Finance, Maintenance, Facilities, Planning and Materials departments. Interaction activity involves providing engineering expertise with deliverables in the form of formal reports and presentations, data analysis, new equipment and process implementation, and improved product and platform configurations.

WORK ENVIRONMENT:

- The work environment characteristics are representative of an office, laboratory and manufacturing environment. Flexible work hours to meet project deadlines.

PHYSICAL DEMANDS:

- Position requires ability to lift up to 25 lbs., work within restricted areas confined by equipment. Up to 50% of time/work within a low humidity environment with potential exposure to biological, toxic and corrosive reagents; and up to 50% is required to work within the confinements of a cubical style office, and also within a laboratory setting. Walking, standing and sitting for long periods of time are routine to accomplish tasks in this role. Specific vision abilities required by this job include close and distance vision and the ability to adjust focus. Must be willing to work 1st or 2nd shift. Position requires use of Personal Protective Equipment as posted.

Education/Experience

- Associate Manufacturing Engineer: BS in an engineering discipline with no industrial experience or equivalent experience.
- Manufacturing Engineer: BS degree in an engineering discipline, preferably Mechanical, Manufacturing, or Industrial Engineering, or equivalent experience. Two to five years' experience, preferably in a pharmaceutical or medical device environment.

- Senior Manufacturing Engineer: BS degree in an engineering discipline, preferably Mechanical, Manufacturing or Industrial Engineering, or equivalent experience. More than five years of experience in a pharmaceutical or medical device environment.

Knowledge/Skills

- Prefer experience in Electrical-Mechanical Theory & Application, Process and Assembly Automation, 2D & 3D CAD, Hardware Design, Pneumatics, Instrumentation, PLC and Machine Programming, Basic Finance Theory, basic quality tools, advanced problem solving, excellent written skills.
- The Manufacturing Engineer must take a proactive approach to the performance of job assignments with minimal input from supervision. Required problem-solving skills include equipment troubleshooting, process debugging through data analysis, implementation of alternate manufacturing techniques and innovation that improves product and process efficiencies. This position requires decision making to a level that can affect overall manufacturing efficiency, which may impact direct cost margins. Problem solving and decision making skill requirements are outlined as follows:

Interested parties should send their resume to: joshciardelli@peaktechnical.com