

Principal Manufacturing Engineer 2011.129

Resumes should be sent to: careers@osteomed.com

In Subject Line must Reference: (Job Code: 2011.129)

Job Summary:

The Principal Manufacturing Engineer supports the continued growth and success of OsteoMed by developing and refining current and future processes critical to the success of the company. To enhance future growth of the company, corporate business objectives and direction need to be understood and modifications to current processes that will aid in achieving these objectives that need to be implemented. Additionally, the future development of new products will likely involve the understanding and successful implementation of new processes.

Duties & Essential Job Functions:

- Performs standard manufacturing engineering assignments and or works independently, by planning schedules and leading projects of moderate scope. Devises new approaches to problem solving by applying modified or standard manufacturing engineering principles.
- Expected to identify and resolve simple and complex problems by using Lean Six Sigma techniques, including the development of a new design of experiments without assistance. Make detailed observations, analyze data, interpret results, and draw rational conclusions.
- Ability to manage multiple projects simultaneously without supervision. This includes creating detailed and accurate project tasks and schedules, interfacing with project team members and other support personnel and solving project related conflicts and issues.
- Ability to organize and prepare internal or external data and documentation according to company policies for assigned projects. Also able to review and edit internal documentation for other team members. Able to lead in the preparation and presentation of materials for internal technical reviews.
- Complete design concepts, prototypes, analytical models, process validations, documentation, and all other aspects of assigned manufacturing engineering projects according to FDA and ISO regulations and OsteoMed SOP's.
- Provide leadership and technical expertise in the areas of design, development, testing and production scale-up of new packaging components and systems. Define Packaging Cost and roadmap for new devices (New Packaging and Process Technology Development).
- Lead innovation and development involving package design, packaging equipment, test methods, packaging validations and customer requirements related to package design.
- Recommend process, equipment, and package design consistent with company objectives.
- Defines and approves package specifications and associated drawings.
- Develops package testing plans and interprets results as required for various projects.
- Coordinates and performs all activities associated with packaging manufacturing line testing. Innovates and utilizes technical expertise in the development of packaging materials and processes.
- Interface with packaging suppliers to identify quality, production and technology capabilities, technology improvement plans and cost reduction goals.
- Definition and implementation of verification and validation plans and protocols associated with manufacturing engineering projects.

- Lead preparation of manufacturing engineering documentation including: engineering drawings, test plans, manufacturing instructions, design verification and validations, engineering change notices, artwork and other supporting manufacturing engineering documents.
- Performs other assigned duties as determined by the Manufacturing Engineering Manager.

Experience/Skills Required:

- Trained in Lean / Six Sigma discipline and Technical Writing.
- Working knowledge of CAD systems – preferably SOLIDWORKS and Microsoft Office products.
- Able to lead FMEA sessions and select engineering materials.
- Communication: Ability to internally and externally discuss and clearly define key technical and project management issues, with minimal assistance using both verbal and in written methods. Ability to convince management on course of action without assistance using both written and verbal methods.
- Interpersonal: Ability to cooperate and support team members and ability to coordinate interdepartmental activities and to resolve individual conflicts and issues.
- Business Acumen: Require a basic understanding of business and financial impact of project.
- Teamwork: Pursue trust for each team member. Seek and deliver honest feedback to all team members. Committed and accountable to achieving team goals. Abide by team decisions

Required Education/Licensing/Certification:

- Bachelor of Science in Engineering or related field with a minimum of nine (9) years of work experience in the medical device or biotech industry or a Master degree in Engineering or related field and at least seven (7) years of work experience in Medical device or Biotech industry.

Physical Requirements:

- Business casual attire.
- Ability to repetitively lift and carry product weighing approximately 50 lbs.
- Occasionally requires attending corporate functions.
- Occasionally may require travel (5-10%).