

Principal Engineer 2012.002

Resumes should be sent to: careers@osteomed.com

In Subject Line must Reference: (Job Code: 2012.002)

Job Summary:

The Principal Engineer is responsible for supporting the development of new products from concept through commercialization as part of a cross-functional development team. This includes active participation in origination of design concepts, design specifications, design for quality and manufacturing requirements, process/technology development, product verification/validation, project planning, and applicable documentation.

Duties & Essential Job Functions:

- Performs standard 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 engineering principles.
- Expected to identify and resolve simple and complex problems, including the development of a new design of experiments without assistance. Make detailed observations, analyze data, interpret results, and draw rational conclusions.
- Ability to complete standard design and engineering tasks without assistance within the scope of one's core educational expertise. Resolution of technical issues outside one's core educational field requires some assistance. Typical assignments have specific objectives requiring investigation of multiple variables.
- 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, validation parts, documentation, and all other aspects of assigned projects according to FDA and ISO regulations and OsteoMed SOP's.
- Work with surgeons or teams of surgeons to connect clinical experience with design specifications
- Definition and implementation of verification and validation plans and protocols associated with engineering projects.
- Customer and vendor communications related to product development.
- Lead preparation of engineering documentation including: engineering drawings, test plans, manufacturing instructions, design verification and validation, engineering change notices, artwork and other supporting engineering documents.
- Possess strong knowledge of anatomy, physiology, mechanics, kinematics, patent landscape, and other technical fields that are related to your specialization area.
- Ability to set up from scratch and lead cadaver labs and function as an expert advisor in surgeries.
- Other responsibilities assigned by supervisor and including attending trade shows, surgery and general corporate functions associated with role as an Engineer

Experience/Skills Required:

- Proficient in SolidWorks or equivalent modeling software and Microsoft Office products.
- Versed in Computational Stress Analysis, GD&T, Tolerance Stack-up, Design Control
- Able to lead FMEA sessions and select engineering materials.
- Trained in Six Sigma discipline and Technical Writing. Proficient in GxP practices.
- 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 (B.S.) degree in Biomedical or Mechanical Engineering with a minimum of nine (9) years of experience in the medical device industry, or
- MS degree in Biomedical or Mechanical Engineering with a minimum of seven (7) years of experience in the medical device 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%).