



Principal Quality Engineer –CMF – 2011.94

Resumes should be sent to: careers@osteomed.com

In Subject Line must Reference: (Job Code: 2011.94)

OsteoMed is a leading global innovator, developer, manufacturer and marketer of specialty medical devices, surgical implants and powered surgical instruments. The company's success is driven by its ability to develop and deliver innovative, quality products that improve patient outcomes and offer technically advanced, simple and cost effective solutions for its surgeon and hospital customers. Our state of the art manufacturing facility and world headquarters is located in Dallas, Texas. OsteoMed specializes in small bone reconstruction and trauma surgical devices targeted primarily to the Oral Maxillofacial, Neuro, Plastic Reconstructive, Otolaryngology (ENT), Upper and Lower Extremity small bone surgical specialties.

Job Summary:

The Principal Quality Engineer is responsible for supporting all quality engineering activities to support the product life cycle, from development of new products (NPD) from concept through commercialization, through sustaining changes, 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. Responsible for all aspects (product and process) related to the quality of the designated product line(s). This includes manufacturability of products, supplier manufacturing, and investigation of customer complaints. Develops, modifies, applies and maintains quality standards, and generates protocols and reports. The Principal QE provides coaching to Design Engineers and Manufacturing personnel on Quality System Requirements and process improvement methodologies for their product families.

Duties/Essential Job Functions:

- Independent self starter who is capable of planning schedules, control plans and leading projects as assigned, who is able to incorporate FDA, ASTM and ISO standards through the product life cycle, designing and developing the required inspection and process control methodologies
- Provide authoritative guidance about Six Sigma principles (Sampling, Acceptance Criteria, DOE, Statistical Process Control, Root Cause Analysis, FMEA, control charts, capability analysis) as well as guidance on Design Control elements to New Product Development team members and Manufacturing Staff
- Develop and execute verification and validation plans and protocols associated with product/process quality according to FDA and ISO regulations and OsteoMed SOPs.
- 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.
- Support supplier audits to ensure supplier capability including reconciliation of inspection methods, and evaluation of proposed vendor changes for NPD and sustaining activities
- Reviews ECN's to ensure compliance to Quality System, QSR and International requirements for New Product Development (NPD) and Sustaining activities
- Support person for Design History File during 3rd party inspections
- Estimate and gather necessary information on timelines and cost related to QA/QC tasks for Project Planning

- Perform hazard and risk analysis for new products and sustaining products, including DFMEA and PFMEA
- Perform investigations for issues affecting product quality post-launch.
- Act as liaison between QC and project engineers to ensure that inspection process capabilities have been verified and appropriately documented
- Other responsibilities assigned by supervisor and including vendor site audits, attending surgeries and general corporate functions associated with role as Quality Engineering professional

Experience/Skills Required:

- 7 – 9 years work experience in a Quality Engineering role, in the implantable medical device industry, with a history of successful participation in New Product Development (NPD) teams.
- Strong working knowledge of Design Controls, manufacturing process controls
- Understanding of human factors engineering
- Proficient in GD&T and metrology. Able to read detailed blueprints and follow assembly instructions, develop inspection plans and evaluate CMM programs. Gage R&R preferred.
- Ability to use metrology and statistical methods to diagnose and correct improper quality control practices, with experience in CMM Programming, GD&T, Gage R&R and Inspection Plan development
- Demonstrated successful application of analytical quality tools including Six Sigma, Lean, SPC. DFSS training preferred
- Computer literate in various software applications. (i.e. - Word, Excel, Access, Minitab.) Solidworks experience preferred
- Independent organization and prioritization of multiple tasks
- Able to lead DFMEA and PFMEA sessions as required
- Communication: Ability to internally and externally discuss and clearly define key technical and process development issues and independently develop course of action/plans
- Strong technical writing skills and ability to create technical protocols and reports as well as manufacturing/inspection procedures
- 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.
- Experience in Lean, Six Sigma and Process Validation/Process Capability
- ASQ CQE/CSSBB or equivalent preferred

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%).