

Job Posting for Senior Quality Engineer or Quality Manager (DOE)

Company: Orchid Orthopedic Solution

Location: Santa Ana, CA

Hiring Manager: David Vu at david.vu@orchid-ortho.com

General Responsibilities Include:

1. Understands how to read basic inspection tools (micrometer, caliper, optical comparators, dial indicators, and CMM concepts).
2. Leads efforts to identify, develop, and execute process improvement initiatives, which focus on cost reduction, improved quality, process efficiency, process stability and standardization leading to increased revenues and customer satisfaction using Lean and Six Sigma techniques.
3. Executes process improvement projects and manages progress through regular status reviews and completion of tasks. Identifies and eliminates barriers preventing progress.
4. Supports business performance with emphasis on customer focus, corrective actions, poka-yoke development, process development, and internal audit systems.
5. Participates in and lead structured problem solving teams and apply statistical and other problem solving tools.
6. Reviews FMEA, inspection forms, and routers before beginning production to provide teams an opportunity to review processes, customer special requirements and equipment/control methods for preventing failure modes from occurring.
7. Reviews written reports summarizing the results of conducted studies making recommendations relative to changes in processing, engineering requirements and product assurance techniques. Reviews statistical control charts for the purpose of monitoring product and process quality characteristics.
8. Provides support to quality management and interfaces with customers, suppliers, engineering, purchasing, and manufacturing on quality related issues.
9. Effectively coordinates and communicates with management and provides reports on the status of NCMRs, RMAs, SCARs, and/or CAPAs.
10. Promotes awareness of the quality, safety, and business objectives throughout the organization.
11. Identifies areas of risk based on the quality management systems assessments, reports findings internally and externally, and monitors the resolution of any identified discrepancies.
12. Leads and facilitates cross-functional project teams to seek, share, and implement best practices across the organization.

Quality Systems Requirements:

1. Oversee Quality System Specialist to effectively manage change control by identifying effects of risks with change proposals, maintaining drawings, and customer requirement files
2. Coordinate CAPA activities by heading CAPA Board with cross-functional inputs. Will need to also lead problem solving sessions using root cause tools, such as cause and effect, and recommend corrective actions/improvement activities.
3. Conduct internal quality/process audits to ISO 13485 and Part 820 requirements and provide training to establish process layered audits
4. Develop and/or refine standard operating procedures (SOP's) and work instructions.
5. Manage personnel in the processing of customer complaints and provide communication to internal stakeholders for efficient investigation.
6. Manage personnel in the coordination of gage and calibration management duties
7. Understand risk management to apply to corrective action decisions.
8. Maintain KPI's and apply systems and controls to maintain performance.

Quality Control Requirements:

1. Oversee quality inspection team led by a QC Working Lead to mitigate inspection bottlenecks through proper inspection system planning.
2. Ensure good documentation practices (GDP) is adhered for batch record documentation.
3. Coordinate the collection and analysis of statistical data to determine and maintain quality products through areas such as cost of poor quality.
4. Understand application of SPC and control charts to maintain specified in-process quality control points.
5. Manage personnel in the processing of internal NCMR's and participate in MRB review.
6. Utilize lean manufacturing techniques and tools to drive operational efficiencies.
7. Review and propose new technologies and equipment with cost justifications.
8. Apply GR&R concepts to control measurement system analysis.
9. Understand mechanical gaging as well as programmed inspection methods such as vision system and CMM.

Skills Needed:

1. Must be able to communicate both verbally and in written form in English.
2. Computer experience with ERP systems and MS Office program suite is necessary to assist in the tracking and reporting of key departmental metrics.
3. Use of knowledge/expertise to make suggestions for quality/productivity improvements and implement changes where possible.
4. Understanding of problem solving tools such as cause and effect diagram, affinity diagram, 5 Whys, check sheets, and flowchart.
5. Ability to manage multiple projects concurrently.
6. Excellent teamwork, organizational, and time management skills.
7. Strong leadership skills and ability to work independently.
8. Knowledge of statistical process control and software such as Minitab.
9. Excellent analytical problem-solving skills are required, along with a high level of self-motivation.

Educational and Industry Knowledge Applications:

1. Minimum BS degree from four-year college or university or equivalent education and experience.
2. 7+ years work experience that has provided a strong understanding of the manufacturing environment and quality control inspection.
3. Experience managing and leading a diverse workforce with technical aptitudes.
4. Employee must be able to work extended hours and have the ability to work in a fast-paced environment.
5. GD&T and blue print reading understanding a plus.
6. Experience with lathe and mill machining desirable.
7. Work performed in office and manufacturing environments.
8. Must be eligible to work in the US.

Working Environment Expectations:

1. Assignment Complexity – Works on assignments that are often complex in nature and judgment is required. Undertakes complex project management assignments to support the department and business needs.
2. Accountability/Discretion – Manages procedures / projects and works under limited supervision.
3. Working Relationships – Interfaces with internal/external customers, suppliers, and all functions within Orchid.
4. Conditions – Works in normal office conditions and in manufacturing areas containing CNC machines.