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**POSITION**: QUALITY MANAGER

4WEB Medical Inc. has a position open for a Quality Manager:

**JOB DUTIES**: Lead supplier qualification activities, with responsibilities including but not limited to supplier selection, qualification, agreements, on-site and desk audits, supplier change requests, supplier corrective actions, supplier reassessments; Conduct supplier performance reviews by consolidating metrics for supplier corrective actions, supplier change requests, and overall supplier performance including scrap rate, product quality, responsiveness, and process deviations; Lead communication with suppliers to improve performance and ensure timely completion of all quality-related activities, including in-process rework, deviations, nonconformances etc; Handle CAPA systems, ensuring investigations, root cause determination, implementation, and effectiveness checks are adequately addressed and documented in a timely manner; manage complaint handling from initiation to closure and assist in submissions of adverse events/MDRs to regulatory agencies; manage document control process to ensure design and document change requests are reviewed implemented in a timely manner; conduct material review and present at material review board meetings to review nonconformances of products and processes; develop and monitor metrics for nonconforming (NCR) products and processes and present complaints at monthly cross functional team meetings; interpreting CAD drawings and manufacturing specifications with a basic understanding of GD&T and use skills to perform inspections of standard implants, instruments, trays, caddy, first articles, semi-finished implants, and patient-specific devices; Perform failure investigations for Corrective and Preventive Actions (CAPA), including root cause analysis, CAPA implementation, and effectiveness verification; Create procedures, work instructions, quality manuals, and product specifications for the quality system in compliance with ISO 13485 and 21 CFR 820; In charge of managing internal audits. Serve as subject matter expert (SME) for complaints, reportable events, documentation control, and product approval; Serve as a trainer and mentor to interns/junior quality staff/direct reports; Perform the annual performance reviews where applicable; Develop and improve processes, systems within 4WEB’s quality management system including filling Quality System gaps with compliant SOPs and Processes; Drive the preparedness activities for audits from Notified Bodies, FDA and customers; Support the audit team before and during inspections; Maintain and update the GS1 and GUDID databases. Support acceptance activities at incoming, review and approve quality records such as IMSs, DHRs, NCRs.

**EDUCATION AND EXPERIENCE**: Bachelor’s Degree or foreign equivalent in Biomedical Engineering, Medical Electronics or related field and three 3 years of experience in the job offered or three (3) years of experience managing complaint handling from initiation to closure and assist in submissions of adverse events/MDRs to regulatory agencies; managing document control process to ensure design and document change requests are reviewed implemented in a timely manner; conducting material review and present at material review board meetings to review nonconformances of products and processes; developing and monitoring metrics for nonconforming (NCR) products and processes and present complaints at monthly cross functional team meetings; interpreting CAD drawings and manufacturing specifications with a basic understanding of GD&T and use skills to perform inspections of standard implants, instruments, trays, caddy, first articles, semi-finished implants, and patient-specific devices; Performing failure investigations for Corrective and Preventive Actions (CAPA), including root cause analysis, CAPA implementation, and effectiveness verification; Create procedures, work instructions, quality manuals, and product specifications for the quality system in compliance with ISO 13485 and 21 CFR 820;

**LOCATION**: Frisco, TX. 40 hrs/week. M-F. Must be authorized to work in the U.S. Email resumes to [hr@4webmedical.com](mailto:hr@4webmedical.com) or mail to Attn: HR, 4WEB Medical, Inc., 2801 Network Blvd. #620, Frisco, Texas 75034. Please mention Job ID #1916.