



JOB TITLE: DIRECTOR OF QUALITY

EDUCATION AND EXPERIENCE: Master's Degree or foreign equivalent in Biomedical Engineering or related field and five (5) years of experience in the job offered or five (5) years of experience providing support to all departments to ensure compliance with 4WEB's quality system and continuous improvement efforts; leading quality and regulatory activities associated with new product development including risk management, supplier qualification, process qualification, and regulatory pathways; implementing multiple product and process improvements as the Corrective and Preventive Action (CAPA) coordinator and owner, to address nonconformances from Notified Body audits and customer complaints; Developing quality metrics and coordinated with the quality team to collect and analyze data for annual management reviews; Participating in weekly Material Review Board (MRB) meetings to review and provide input on product dispositions for open nonconformance reports;

JOB DUTIES: Implement and maintain an effective, compliant Quality Management System; Provide leadership and oversight for all quality system processes; Provide support to all departments to ensure compliance with 4WEB's quality system and continuous improvement efforts; Lead quality and regulatory activities associated with new product development including risk management, supplier qualification, process qualification, and regulatory pathways; Define and implement an ISO13485 and 21CFR820 compliance Quality Manual and Quality Policy; Lead and support change control processes for all design and QMS processes; Ensure adequate resources are in place to control and maintain documents and records; Act as management Representative for all 4WEB Medical facilities; Host external audits by 3rd parties (FDA, Notified Body, Customer, etc.); Ensure proper risk analysis controls, tools and practices are in place; Lead creation and tracking of quality objectives for all departments; Report to leadership team on the status of the quality system and quality objectives; Lead Management Review activities, guide quality and other teams to compile metrics showing the effectiveness of the QMS; Define requirements for the training program and ensure resources and curriculum are available to meet training needs; Monitor effectiveness of the training program; Partner with R&D, Supply Chain and Operations leadership to ensure facilities and work environment are adequate to achieve product conformity; Lead and support quality team through the product realization process from customer inputs, through design controls and design transfer to outsourced manufacturing partners; Ensure 4WEB quality team has adequate equipment and capabilities ensure that all products meeting acceptance criteria; Provide oversight to ensure suppliers are selected and qualified to meet expectations including quality expectations; Monitor supplier performance to ensure expectations are met; Define and implement monitoring and measurement of product and processes to ensure requirements are met; Partner with Operations Leadership to ensure internal production processes are adequately defined, implemented and monitored; Ensure systems for product identification and traceability are in place and adequate; Provide adequate infrastructure and resources for calibration and preventive maintenance activities to be performed; Provide oversight to the complaint handling process including MDR/Vigilance reporting determinations and decisions related to product field actions and recalls; Ensure internal audits are conducted per policy and that results are reported to leadership; Lead quality engineering team to investigate and resolve product and process non-conformances; Define and effective CAPA system and ensure adequate

resources are available to investigate and resolve CAPAs in a timely manner; Implement multiple product and process improvements as the Corrective and Preventive Action (CAPA) coordinator and owner, to address nonconformances from Notified Body audits and customer complaints; Developed quality metrics and coordinated with the quality team to collect and analyze data for annual management reviews; Participated in weekly Material Review Board (MRB) meetings to review and provide input on product dispositions for open nonconformance reports; Ensure FDA and Notified Body submissions are complete and accurate; Interact with regulatory agencies as required; Draft various QA SOPs and other relevant documents to QMS; Conduct audits of various suppliers, contractors and vendors; Ensure evaluation of, and reporting on, vendor quality systems; Manage the monitoring, measurement, and review of internal processes, especially those that affect the quality of the organization's products; Build a strong Quality team by hiring qualified candidates, establishing and actively managing performance expectations and providing training and mentoring to staff.

LOCATION: Frisco, TX. 40 hrs/week. M-F. Must be authorized to work in the U.S. Email resumes to hr@4webmedical.com or mail to Attn: HR, 4WEB Medical, Inc., 2801 Network Blvd. #620, Frisco, Texas 75034. Please mention Job ID #1915