TEKIA

THE OFFERED POSITION: Quality Manager

DETAILS:

Name of the employer: TEKIA, Inc.
Address: 17 Hammond Suite 414 - Irvine, CA 92618
Apply by fax: (949) 699-1302 Attn.: Gene CURRIE, CEO

Job Duties:

- Planning, scheduling & conducting Internal Audits of the Quality System per ISO 13485, medical device directives and 21CFR 820 regulations.

- Creates and maintains Quality Assurance Manual (QAM) and formulates Quality Assurance and Quality System objectives and activities in accordance with applicable regulatory agency requirements and standards (FDA and European regulations, ISO 13485/2012 and sterilization International standards); Understands and communicates in the company applicable regulatory requirements related to Asian market, in particular India, Taiwan, China and Korea.

- Representing firm in external audits (Notified body, FDA, MFDS) for areas under my responsibility.

- Investigating and documenting Customer Complaints, Non-Conformances based on root cause analysis. Performing risk-analysis and implementing a corrective and preventive action plan (CAPA).

- Systematically analyzing and summarizing the progress of the ongoing projects, quality objectives and goals set in the QIP (Quality Improvement Plan) for management reviews.

- Preparing validation protocols and performing validations (IQ, OQ, PQ) of manufacturing processes including pre-production runs, equipment & software (ERP, equipment software, labeling database).

- Managing the calibration, maintenance and environmental monitoring program, ensuring facility and equipment are within specification & are complaint with external standards & internal procedures.

- Performing trend analysis of critical parameters to monitor the manufacturing process & environment.

- Developing, writing, updating test methods, operating procedures and manufacturing procedures to facilitate continuous conformity.

Location of Job opportunity: 17 Hammond Suite 414 - Irvine, CA 92618

Job requirements: BS in Biomedical Engineering or related + 3 months of experience