HEAD OF QUALITY

KVK seeks Head of Quality in Newtown, PA to manage and lead all quality functions (Quality Assurance, Quality Control and Technical Services) and ensure implementation of quality policies, SOPs, resources and systems in compliance with cGMP & FDA regulations/guidance for manufacturing and distributing pharmaceutical products at our sterile and non-sterile dosage form facilities; participate as a lead in key regulatory inspections such as by US FDA, DEA etc. and oversee remediation of US FDA Warning Letters; lead quality and technical services teams for sterile and non-sterile dosage formulations; establish and monitor Quality Metrics for measuring KPIs such as market complaints, valid & invalid Out of Specification Results, Deviation rate, CAPA, Change Controls, Annual Product Quality Reviews etc.; oversee and manage corporate Quality Assurance department by establishing policies, goals, objective and timelines; manage our quality control laboratories involved in testing and releasing raw materials, packaging materials, finished products, stability samples, Non-sterile, & Sterile dosage forms etc.; ensure manufacturing and distribution in compliance with CFRs, key regulatory policies and requirements related to Quality by Design, Technology Transfer, Quality Risk Management, Knowledge Management, Product and Process Understanding, Stability Studies, Process Validation, Data Integrity etc.; Guide, train and mentor quality and tech services leaders at our sterile & non-sterile manufacturing sites etc. among others. Master's degree or foreign equivalent in Chemistry/Pharmaceutical Science or related field and ten (10) years relevant work experience required. At least 5 years of the required 10 years work experience must be in pharmaceutical product development/ leading quality operations/teams/ managing product technology transfers. Mail resume to HR Manager, Attn: QltyHead, KVK-TECH Inc., 110 Terry Drive, Ste. 200, Newtown, PA 18940.