Quality Control

At Kotra Pharma, we believe that everyone deserves a healthier tomorrow. It's every individual's right to live a healthy life to the fullest, and thus, we are committed to bring top-notch health products to the world. By humanising healthcare, we see beyond instruments and medicines for the general well-being of everyone. If you want to make a difference in this industry, begin with us.

Senior Chemist or Analytical Method Development Chemist	**<u>Key Responsibilities:</u>** * To report to QC Manager on all matters related to analytical method validation and analytical method development or improvement for existing starting materials and finished products. * Establish analytical method validation protocol, execute and prompt reporting analytical method validation reports on timely manner. * Responsible to establish and manage all the analytical method validation and method development or improvement related documentation system and archival. * Direct assistance to Validation Team in process validation, cleaning and other qualification or validation, in which laboratory testing support is required. * To work towards achieving the QC Departments KPI. * To ensure a safe working environment at QC Department. * Comply and work towards meeting the company's quality, health safety and environment objectives and policies. * Any other jobs or assignment as assigned. **<u>Job Specifications:</u>** * Bachelor Degree or Master in Chemistry/ Food Science/ Pharmacy or equivalent. * At least 3 to 5 years working experience in analytical pharmaceutical, healthcare or cosmetic manufacturing industry. * Hands on experience in validation of analytical procedures in line with the development of new formulations * Strong working knowledge in product developed compliance to cGMP, National Regulatory Guidelines and other law regulating the manufacturing and commercialization of medical products. * With good command of spoken and written English.

Chemist	**Key Responsibilities:** ∗ To report to QC Manager on all matters related to analytical method validation and analytical method development or improvement for existing starting materials and finished products. ∗ Establishing, managing, planning, scheduling and executing analytical method validation and analytical method development or improvement programs for existing starting materials and finished products following regulatory requirements. ∗ Responsible to review and establish finished product and starting material test procedures, specification and COA in accordance with latest official monographs/pharmacopoeia. ∗ Responsible to train and qualify QC chemists and lab technician on development or improved analytical methods for existing starting and finished products. ∗ Direct assistance to the Validation Team in process validation, cleaning and other qualification or validation, in which laboratory testing support is required. ∗ To participates in troubleshooting laboratory equipment failure and provide proposals for improvements. ∗ To work towards achieving the QC department KPI. ∗ To ensure save working environment at QC department. ∗ Comply and work towards meeting the company's quality, health safety and environment objectives and policies. **Job Specifications:** ∗ Bachelor Degree or Master in Chemistry/ Food Science/ Pharmacy or equivalent. ∗ At least 3 to 5 years working experience in analytical pharmaceutical, healthcare or cosmetic manufacturing industry. ∗ Hands on experience in validation of analytical procedures in line with the development of new formulations. ∗ Strong working knowledge in products development and familiarity with quality assurance procedures. ∗ Knowledge in new products developed compliance to cGMP, National regulatory Guidelines and other law regulating the manufacturing and commercialization of medical products. ∗ With good command of spoken and written English.

Microbiologist	**Key Responsibilities:** ∗ Reports to Quality Control Manager on all matters pertaining to Microbiological Quality Control Laboratory Activities. ∗ Responsible for matters relating to work efficiency, personal safety, personnel hygiene, appraisal and discipline of Microbiology Laboratory staff. ∗ Planning, scheduling and supervising microbiology testing for starting material, packaging material, intermediate samples, stability samples and finished products and ensure the testing performed in compliance with GMP, GLP and Good Aseptic Technique. ∗ To do purchasing, receiving and stock keeping of all material and media required in Microbiology Laboratory operations. ∗ To monitor the stock reference cultures and ensure the correct usage of biological indicators. ∗ To assist R&D department and provide technical support for QA and other relevant departments pertaining to microbiological testing and validation. ∗ To participate in any activities pertaining to training, safety, first aid and fire fighting organized by the company for the benefits of staff and company. ∗ Comply and work towards meeting the company's quality policy, health safety and environment objectives and policies. **Job Specifications:** ∗ Minimum Degree in Science or equivalent. ∗ Preferably with 1 or 2 years of experience. ∗ Possess good laboratory and analytical skills. ∗ Possess good technical writing skill. ∗ With good command of spoken and written English.

Laboratory Technician	**Key Responsibilities:** ∗ Reports to Assistant QC Manager on all matters pertaining to laboratory equipment status involving availability, preventive maintenance, calibration and qualification. ∗ Responsible in ensuring that all the laboratory equipment are always in an idle status for use. ∗ Responsible in conducting calibration, and preventive maintenance according to the predetermined schedule. ∗ Responsible in coordinating for external calibration and preventive maintenance for laboratory equipment as per schedule. ∗ To update the laboratory equipment master list, in order to reflect the current number and status of the equipment. ∗ To ensure that all equipment records are maintained and archived in equipment files.

	* To immediately report to Superior on any deviation observed on laboratory equipment. * To assist Superior in preparing yearly equipment budget for Quality Control Department. * To strictly follow to safety regulations during daily work and safety precaution of each equipment. * To practice GMP and GLP at all times. * Establish were and tare or spare part list for critical instruments and ensure stock keep of the spare parts. * Establish and review SOP's related to equipment / instrument operating procedures and calibration procedure accordingly. **Job Specifications:** * Minimum qualification Diploma in Mechatronics/ Electronics/ Mechanical. * Preferably with working experience, but fresh graduate are encouraged to apply. * Preferably below 30 years old.

Interested candidates are encouraged to apply. Kindly send your resume to:

Recruitment, Human Resource Department
Kotra Pharma (M) Sdn Bhd (90082-V)
No. 1, 2 & 3 Jalan TTC 12, Cheng Industrial Estate
75250 Melaka, Malaysia

Or

E-mail to: hr@kotrapharma.com