Maha El-Sayed Mohamed Essawy

**Personal Data**

:

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: Mahaessawy@yahoo.com

: March 8, 1972

* + - **Address**
    - **Mobile**
    - **E-mail**
    - **Date of birth**

**Education:**

* + - **May 1994 - Bachelor of pharmacy, Zagazig University, Grade: Very good**

**Languages:**

* + - **English:** Very Good

**Computer Skills**

* + - **MS Windows & MS Office package.**

**Professional Experience:**

* **June 2015 till now – Quality Control Manager – Cephalosporin Factory - Medical Union Pharmaceutical (MUP)**
* Responsible for assessing compliance of laboratory practices, implementing current best practice methodology and compliant system that meet cGMP, MOH regulations, WHO standards and ISO requirements.
* Facilitate and lead efforts for continuous improvement in QC work practices.
* Ensuring that API and packaging material specification of the company and its suppliers are complying with pharmacopoeia and in-house specifications.
* Evaluate all data generated by QC laboratories and accordingly accepts / rejects raw material, packaging material and finished products through review and approval of analysis reports and COA's.
* Identifying quality-related training needs and establishing internal and external training programs in coordination with the HR department.
* Research and study of the problems facing worker in the department to resolve them and provide them with advice and technical guidance.
* Supervise investigation of all cases of not conformance and or out of specification results, of products, raw materials and packaging materials and follow conduction of route cause analysis and guide the team to the right corrective or preventive action should taken.
* Review and approve SOP's, Specification sheets and method of analysis.
* Review and approve process validation protocols of all products, cleaning validation protocols, method validation protocols and reports.
* Approve re-registration files of under license, toll manufactured products.
* Ensure all methods and equipment are suitable for supporting site production via development and execution of appropriate qualification / validation plans.
* Makes sure that required safety instructions are fully implemented.
* Ensure that waste treatment is carried out according to up-to-date regulations.
* Following the results of internal, external audits and proposing the suitable corrective actions in time.
* Responsible for following exact implementation of quality policies, standards and procedures.
* Responsible for following the study and analysis of complaints in the different QC departments.
* Ensure that the calibration and maintenance of laboratory equipment of his department are performed in time.
* Approve maintenance contracts of equipments offered by external service agents.
* Work on development of technical and scientific and soft skills for employees in all QC departments and propose trainging programs for them.
* **July 2013 to June 2015 – QC Validation & Ongoing Stability Manager – Medical Union Pharmaceutical (MUP)**
* **January 2012 to July 2013 – QC Validation & Ongoing Stability Section Head – Medical Union Pharmaceutical (MUP)**
* Supervision of the analysis results of the stability products till end of shelf life.
* Responsible for supervising cases of non conformance and or out of specification results and conduct route cause analysis in and guide the analyst to the right corrective or prevent ice action should be taken.
* Responsible for supervision of the achievement of validation program in the QC department.
* Responsible for supervision of the achievement of the cleaning validation program of all production departments.
* Responsible for accomplishing the issue of new standard operating procedures, periodic revision and updating of these SOPs and assuring that modification is consistent with quality policies.
* Responsible for exact implementation of quality policies, standards and procedures.
* Responsible for following the results of internal, external audits and proposing the suitable corrective actions in time.
* Follow-up work to provide all the necessary administration of standard materials, laboratory reagents, tools and present it to the QC director.
* Follow-up laboratory equipment calibration, whether internal or external calibration.
* Follow-up training of analyst on SOPs.
* Work on development of technical and scientific skills for workers in his department and propose training programs for them.
* **January 2008 to January 2012 – Responsible for Stability and Cleaning Validation in QC**
* Prepare cleaning validation protocols, follow up the implementation of these protocol.
* Review the analysis results of cleaning validation samples and report the results.
* Prepare stability plan and follow up the implementation of the plan.\
* Review the analysis results of stability samples and record the results in stability tables.
* **January 2001 to January 2008 – Quality Control Supervisor**
* Physical and chemical analysis of finished products.
* Calibration of instruments (Bio-Dis Dissolution apparatus, Waters HPLC, Agielent HPLC and Dissolution apparatus).
* Validation of test methods.
* Training of new employee.
* Review of analytical results.
* **August 1994 to January 2001 – Quality Control Specialist**
* Physical and chemical analysis of raw materials and finished products.
* Preparation and standardization of volumetric solutions.

**Training:**

* + - **Good Manufacture Practice (GMP).**
    - **Good Laboratory Practice (GLP).**
    - **ISO 9001.**
    - **Quality Management and SOP writing.**
    - **Total Quality Management (TQM) and Statistics.**
    - **Infra-red spectroscopy.**
    - **Gas chromatography.**
    - **Bio-Dis Dissolution apparatus.**
    - **Out Of Specifications (OOS) investigations.**
    - **Lab\_Safety.**
    - **Agielent 1100 series HPLC: operation, calibration and use of data chemstation program.**
    - **Alliance waters HPLC: operation, and use of program.**
    - **FIP workshop.**
    - **Internal auditor course.**
    - **Iso 17025**
    - **Training on Pharmacovigilance**
    - **Communication skills**