Ahmed Abd El- Hamid Abd El-Aty Mohamed

El- Zagazig City, El- Sharkia

E-mail Address: Gabr449@Gmail .com

Mobile Phone : 01062136705

PERSONAL INFORMATION

- **Birth Date:** 3rd., July, 1984
- **Nationality:** Egyptian
- **Military Status:** Finally, Exempted
- **Marital Status:** Married

EDUCATION PROFILE

- B.Sc. in pharmaceutical sciences, Al-Azhar university
- Grade: Very Good ﴾2007﴿.
- 24th, January,2006 to 6th February, 2006, Clinical Pharmacology by ICC (International Culture Center)

WORKING EXPERIENCE:

- **Mash premiere Quality Assurance Manager (July 2020 up till Now)**
- **Multi-Apex Pharma.CO**. **as Documentation & GMP Compliance supervisor & deputy for QA Manager (May 2015 to July 2020)**
- **Multi-apex Pharma. Co.** as Documentation officer (January 2014 till April 2015)**.**
- **Multi-apex Pharma. Co.** as an in process control (July 2010 till January 2014).
- **Delta Pharma Co.** As quality assurance inspector in Ware house area (*May 2009 till July 2010).*
- **Delta Pharma Co.** As quality assurance inspector in production area (semi solid, and syrup) (April 2008 till May2009).
- **Work at community Pharmacy** (May 2007 till April 2008)

PRACTICAL EXPERIENCE:

QA Manager.

- Lead Auditor for QMS, ISO 9001.14001.45001.
- Member in Egyptian syndicate of scientific professions.
- Review and Approve results and report for external and internal validation.
- Investigation and Deviation.
- Change control.
- Recall and Complains.
- Follow up all GMP requirement and ISO systems.
- Follow up on-job training, evaluation & motivation of subordinates in Q.A Management.
- Coordination MOH audit with MOH auditor weekly inspection or annually inspection.
- **Documentation & GMP Compliance:**
- Review and Approve Validation Master Plan.
- Review and Approve protocol and report for validation.
- Preparation and review of Standard Operating Procedures (SOPs) to ensure their compliance with regulatory and corporate requirements.
- Approve of all departments' procedures.
- Approve of master batch records.
- Review of site master file.
- Managing the process of change control and combined risk assessment, defining required task for effective implementation and following up its progress and evaluation of change

Validation and qualifications:

- Determine all qualification / validation polices, risk assessment, approaches, priorities, and plans, with Communicating required technical department's managers.
- Prepare and review of all validation master documents (VMP – general procedures and protocols).
- Review and participating in the IQ, OQ & PQ of utilities, machines, / equipment in cooperation with external agent, production, QC & QA (each in his area of responsibility).
- Write and review all Cleaning Validation (CV) protocols and reports for all production machines/ equipment and preparing the worst case selection study of product A & B and preparing product and equipment/ machines groups.
- Prepare and review all Process Validation (PV) protocols for different pharmaceutical products.
- Have overall responsibility for the co-ordination, implementation, and management of all validation activities to meet c GMP requirements.
- Investigating all deviations and/or failures, change controls during the qualification /validation activities and follow-up of the implementation of all required corrective actions and Risk Assessment.
- Prepare and execute the calibration management program for all company equipment.
- Schedule, plan, manage and executing reports of Aseptic (Sterile) validation:
- · Media fill validation.
- · Tunnel validation.
- · Autoclave validation.
- · Oven and Incubator validation.
- Schedule, plan, manage and executing reports of (IQ, OQ and PQ for machines) of manufacturing, packaging, laboratory, utility systems and equipment's accordance with (cGMP), and Re –Qualification cycle.
- · Utilities validation
- · HVAC system.
- · Water system.
- Participating in approval of all required changes in the process after the validation.
- Prepare sample plan and report for holding time in all product steps in different dosage form.
- **Investigation of Deviations**
- Participate in investigations of deviations, identification of root cause and determination of remedial corrective and preventive actions.

- **Internal Auditing**
- Perform audits, prepare action plans, track and follow up observations till closeout of plant departments and functions such as:
- Manufacturing & Packaging (sterile, non-sterile solid, semisolid and liquid).
- Quality Control (Microbiology, Methodology, Chemistry & Stability).
- Quality Assurance.
- Validation.
- Warehouses.
- Engineering.
- Research and development.
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- **External Auditing**
- conducting packaging suppliers auditing for evaluating the suppliers' quality system, issuing an auditing report contains the observations and final approval or rejection for the supplier.
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- **In-Process Control:**

- solid dosage form:
    - Inspection on preparation process and filling process, perform all IPC tests (weight, leakage, hardness. thickness. dissolution. Over printing).
    - Sampling of IPC and finished product.
    - Inspection on cleaning of machine and line clearance.
- semi solid, and syrup:
    - Inspection on preparation process and filling process, perform all IPC tests (weight, leakage, clarity, PH, over printing).
    - Inspection on cleaning of machine and line clearance.
    - environmental monitoring
- Ware house area:
    - Inspection all activities in dispensing area.
    - Working in quarantine area for finished product
    - receiving raw material, packaging material and sampling it for analysis
    - Release raw material, packaging material.

- **Instrumental use:**

- PH meters.
- Conductivity meter.
- Hardness
- Thickness
- Leakage test
- Friability test
- Viscometer

TRAINING COURSES

- ISO 17025 Awareness
- Certified ISO 9001:2015 (team quality ISO Certification body)
- Certified 14001:2015 (team quality ISO Certification body)
- Certified 45001:2018 (team quality ISO Certification body)
- Certified Lead auditor ISO 9001:2015 (ASCB – USP)
- SOPs Writing (pharma arena for training)
- Tablet &capsule manufacture (prepared the material by DR. Adel sakr)
- Computer system validation
- Water for pharmaceutical Use.
- ERP system. Internal training
- GSP. Internal training
- GMP Advanced (EDA course)
- CTD course. Internal training
- Cleaning validation (pharma arena for training)
- Process Validation (pharma arena for training)
- Validation practices &master plan (pharma arena for training)
- HVAC system (EDA course)
- Quality risk management. (EDA course)
- Pharmaceutical Waters system (pharma arena for training)
- SAP system (Internal training)

COMPUTER SKILLS

- Use ERP System Soft ware
- SAP system
- Excellent in Microsoft office
- Excellent in Internet use
  - Access to Information.
  - Search in different search engines.
  - Research purposes
  - Use Mini tab program in data analysis

PERSONAL SKILLS

- Self motivated. Hard Worker, Work under Stress, Flexible, Have creative Thinking.
- Able to understand the interrelate nature of different systems and tasks.

TRANSCRIPT AND OTHER DOCUMENTS ARE TO BE SUBMITTED UPON REQUEST