CURRICULUM VITAE

PERSONAL INFORMATION

Name : Tarek Mahmoud Mohamed Mahmoud Kotb

Gender : Male

Date of birth : 20-09-1984

Postal Address : Obour city - 3 rd district - Egypt.

Nationality : Egyptian

Marital Status : Married

Military Service : Finally Exempted

E-Mail address : Dr.tarek4ever@gmail.com

Mobile Number: 002 - 01224205814

EDUCATION

- **Bachelor's Degree of Veterinary medicine (June 2006)**
  General appreciation:- good
  From: - Assiut University, Faculty of Veterinary medicine.

- **Diploma degree –** as post graduate studies **– Cairo university (November 2008)**
  In the branch of Medical Microbiology
  General appreciation: good

- **Certified manager of Quality / Organizational Excellence (CMQ/OE) from ASQ institute**
  Certification from American Society for Quality 2015.

- **ISO 9001 lead auditor**
  Certification from IQMS - UK

SUBJECT

- **Job title:**
  - Quality Assurance manager
  - Validation and Qualification manager
  - Quality assurance external auditor
  - ISO 9001 lead auditor

PERIOD OF EXPERIENCE

- **Period of Experience :-**

- From August 2022 till now – in ROTABIOGEN (Hefny Pharma Group) ***Aseptic***
- From July 2010 till August 2022 - in Copad Pharma – Obour City– Egypt.
- From December 2018 till August 2022 – in Copad Nutrition - Obour City- Egypt.
- From June 2006 till July 2010 - in T3A Industrial – Assiut – Egypt. ***Aseptic & Non aseptic***

WORK EXPERIENCE

- **Site of experience:**

  T3A industrial - factory (Aseptic & non aseptic solid, semisolid, liquid)

  COPAD PHARMA factory and COPAD NUTRITION factory - (Oral solid dosage)

  ROTABIOGEN (Hefny Pharma Group) - (Aseptic)

- **Field of Experience :**

A) Quality Assurance: at the following companies:-

- ROTABIOGEN (Hefny Pharma Group) - **(Aseptic)** from August 2022 till now
- COPAD PHARMA , Obour City, Cairo, Egypt (QA manager) From July 2010 till now
- COPAD NUTRITION , Obour City, Cairo, Egypt
- T3A Industrial, Assiut, Egypt **(Aseptic & Non aseptic)** From 2006 till July 2010

- **Responsibilities:**
- Preparing for - **COPAD factory startup** - all Quality master documents/procedures activities.
  - Issuing for site master file (**SMF**) of the factory and any technical changes.
  - Issuing for Quality Manual (**QM**) & of the factory as per the latest ICH requirements.
  - Assuring of implementation Good Manufacturing Practice **(cGMP)**.
  - Achieving **ISO**, Quality Management System (**QMS**) &**TQM** requirements.
  - Preparing the site for ISO audits.
  - Reviewing the standard operating procedure and master documents of quality assurance.
  - Product Quality Review (**PQR**) for the different processed pharmaceutical products.
  - Supplier auditing & qualification.
  - Documentation, issuance, archiving, distribution of master documents and Making database for it.
  - Risk assessment and risk study for Risk/Hazard products.
  - Batch revision after the end of the manufacturing & release.
  - Deviation and CAPA handling .
  - Complaints.
  - Recall.
  - Quality Management Review **(QMR)**.
  - Performance qualification of machines and equipment **(PQ).**
  - Release and product dispatching.
  - Reprocessing and repackaging procedures.
  - Self inspection and internal auditing.
  - Validation & qualification activities

B) Validation & Qualification *(Manufacturing science & technology)*

- ROTABIOGEN (Hefny Pharma Group) - **(Aseptic)** from August 2022 till now , *10th of Ramadan City, Egypt (QA manager & Validation and Qualification manager)*
- Copad Pharma , *Obour City, Cairo, Egypt (Validation & Qualification manager)*
- Copad Nutrition , *Obour City*, *Cairo, Egypt (QA manager)*
- T3A Industrial, *Assiut, Egypt (as Validation Section Head)* ***(Aseptic & Non Aseptic)***

- Attending COPAD factory startup regarding Qualification/Validation/Calibration activities as validation team leader for all task force groups regarding to:-
  HVAC system qualification, Water system qualification, Machine qualification, Building qualification, and Calibration program.

- Attending WHO audit on validation section in T3A "Jan 2008", by participating in preparing all the required validation activities as per WHO guidelines and achieving WHO pre-approval.
- **Responsibilities :**
- My responsibilities was divided into:
  - Follow the GMP guides. (European – Canadian – FDA – PICs – PDA – WHO - …..).
  - Preparation of the validation system.
    - *Aseptic Validation*
      - Tunnel validation
      - Autoclave validation
      - Media fill validation
      - Incubators validation
      - Clean steam, compressed air / Nitrogen qualification.
      - CIP/SIP qualification
      - Vial /Ampoule process validation

    - *Non- aseptic validation*
      - Process validation for solid & semisolid pharmaceutical dosage forms.
      - Cleaning validation &verification.
      - Analytical method validation.
      - Computer system validation.
      - Utilities validation :-
        (HVAC system, Water system, clean steam quality tests, compressed air tests..... etc)
      - Shipment validation
  - Design qualification, Building qualification for the factory.
  - URS (User Requirement Specification, DQ (Design Qualification), IQ(Installation Qualification), OQ (Operational Qualification)and PQ(Performance Qualification) for the machines and equipments.
  - Responsible for FAT (Factory Acceptance Test) and SAT (Site Acceptance Test) for equipments and machines.
  - Determination the schedule of qualification for all machines and equipments.
  - Co-ordination of all validation and qualification team.
  - Preparation of validation program and validation master plan (VMP).
  - Preparation of validation SOPs.
  - Preparation of the validation protocols.
  - Preparation of the validation reports.
  - Participating in Preparation of Quality Courses by giving validation training presentations.
  - Participating in approval of all required changes in the process after the validation.

- Partner in investigation of all OOS and deviations.
- General monitoring for the validation results.
- Calibration Program (formation of calibration unit, preparing and qualifying calibration team, finalize all calibration activities by internal team).
- Preparation of supplier qualification reports for suppliers.
- Supplier auditing.
- Preparation of the external audit plan for the suppliers.
- Preparation of ISO documentation and conducting internal ISO audits.
- Preparing and giving Validation training courses (T3A,CID,MEPACO,COPAD PHARMA)

C) Copad Nutrition factory

- Responsibilities:

- Start-up of quality system.
- Qualifying the site for getting approval of the site by NFSA (Egyptian Food Safety Authority) and to be 1st food factory in white list of Egyptian Food Safety Authority.
- Creation and approval of Copad Nutrition factory Quality master documents/procedures activities.
- Issuing for site master file (SMF) and master documents of the factory.
- Assuring of implementation Good Manufacturing Practice (cGMP).
- Achieving ISO 22000 requirements (Food safety) and formation of HACCP team.
- Preparing the site for ISO audits & NFSA audits (Egyptian Food Safety Authority).
- Reparation of ISO documentation & HACCP program and Risk assessment.
- Qualification of machines and equipments (IQ,OQ).
- Utilities validation (Ventilation and air conditioning system, Water system)
- Partner in investigation of all OOS and deviations.
- Calibration Program (formation of calibration unit, preparing and qualifying calibration team, finalize all calibration activities by internal team).
- Preparation of supplier qualification reports for suppliers.
- Supplier auditing.
- Preparation of the external audit plan for the suppliers.

D) Quality assurance external auditor

Conducting site audit for factories and suppliers dealing with Copad Pharma & Copad Nutrition Inside and outside Egypt.

E) ISO lead auditor

Scope: ISO 9001:2015, ISO 45001:2018
ISO 14001:2015, ISO 22000:2018, ISO/TS 22002-1

Auditing on facilities and conducting gap analysis in order to evaluate and prepare facilities prior to ISO certification process.

COURSES, TRAINING AND CERTIFICATES

- I have completed the following training courses and activities below:
  1. Certified Quality manager / Organizational Excellence (CQM/OE) Certification from American Society for Quality (ASQ). – 2015
  2. Accomplishing TQM course – from ASI
  3. Accomplishing Lean manufacturing course – from ASI
  4. ISO preparation course and certification from TQCSI – 2019
     ISO 9001:2015, ISO 45001:2018.
     ISO 14001:2015, ISO 22000:2018, ISO/TS 22002-1
  5. ISO 9001 Lead auditor certification from IQMS-UK
  6. Diploma degree -*as post graduate studies*- in Microbiology from Cairo university 2008
     It includes the following:-
     - Bacteriology (General & Systematic)

- Mycology
- Immunology
- Virology

7. Attending the following courses in T3A industrial pharmaceutical factory Assiut - Egypt :-

1. Training program in Basic current Good Manufacturing Practice (cGMP).
2. Statistical process control and seven quality tools.
3. Six sigma and lean manufacturing.
4. Accomplishment of TOEFL- course – from Assiut University.

SKILLS PROFILE

Personal Skills, Qualities and Hobbies

- I am hard working, neat and tidy, can make friends easily and I am confident meeting new people. I am happy working alone or as a member of a team
- I can relate to and communicate well with others.
- Sports: am athletic person as I am fond of most kinds of sports, a referee in Egyptian Karate Federation.

Computer Skills

- I am confident using Microsoft office package within both Windows 98, XP,7 environments.
- Good command of internet.

Language skills

Good command of English Spoken & Written, I can read and hold a conversation in English.

American Society for Quality

Tarek Mahmoud Mohamed

has satisfactorily fulfilled the requirements established by the Society for professional attainment in

Quality Management

and is, therefore, certified by the Society as a

Certified Manager of Quality/Organizational Excellence

Certification Number	*17665*
Certification Date	*10/4/2014*
Recertify By	*12/31/2017*

Katharine B. Harris
Chair, Certification Board

AMERICAN SOCIETY FOR QUALITY

Stephen K Hacker
Chair

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Certification Number	Date Issued	Recertify By
17665	10/4/2014	12/31/2017

October 20, 2014

65318069
Tarek Mahmoud Mohamed
Copad Pharma
7thQeba st. from ElGlaa St. Asyut, Egypt
Obour City, 2nd industrial zone,Copad Ph
Asyut, Egypt 71111
EGYPT

Dear Tarek Mahmoud Mohamed:

CONGRATULATIONS! The Certification Board is pleased to announce that you have passed the written examination for the ASQ Certified Manager of Quality/Organizational Excellence Certificate. You have reached an important milestone in your professional development.

Certification is not a license. It is peer recognition of proficiency in the prescribed body of knowledge. Please refer to your certification in terms which are consistent with the legal requirements found in many states. We recommend that you refer to yourself as an "ASQ Certified Manager of Quality/Organizational Excellence." It is very important that you associate the Society with your certification.

Enclosed are your certificate and wallet card. Please review this information and call ASQ Headquarters if there are any discrepancies. As a certified individual, the ASQ Code of Ethics should serve as your professional guide.

Technological change is a continual occurrence which erodes the value of professional certification unless the certification is periodically updated. You may choose to recertify by examination or by accumulating the 18 required recertification units. The units should be recorded in your Recertification Journal and submitted to your Section Examining Committee, during the six months prior to the expiration date on your wallet card.

You can be rightfully proud of your certification as recognition of your professional knowledge by your peers in a professional society. Your name will be given to the Chair of your ASQ section for recognition through the Section.

We look forward to your continued participation in the Society.

Sincerely,

iqms Learning

Certificate of Achievement

This is to certify that

Tarek Kotb

has successfully completed a course certified by the Chartered Quality Institute and International Register of Certificated Auditors scheme for Auditing

ISO 9001:2015 Lead Auditor

6th to 10th October 2020

iqms Learning Ltd
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Signed for **iqms Learning**

IQ – LA1098
CERTIFICATE NUMBER
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