MARAM MOHSEN HUSSIEN

Address: Al Azizia, Makkah Al Mokarama, KSA
Telephone: (00202) 2270-4649
Mobile: 01002931744
E-mail: DR_MARAM_MOHSEN@OUTLOOK.COM

EDUCATION

	German University in Cairo, Cairo, Egypt.
(JUL/2014)	**Bachelor Degree**
	Pharmacy, Pharmacy and biotechnology
	Cumulative Grade: Very Good

ACADEMIC ACHIEVEMENTS:

- **Practical Diploma and workshop in Pharmacovigilance given by Dr. Amr Saad (certified from Arab Union of the manufacturers of pharmaceuticals and medical appliances (AUPAM)(2015):**

- **Wave 1:** Development of Pharmacovigilance system master file (PSMF) and PV Quality Systems (Audits and Inspections).
- **Wave 2:** Periodic Safety Update Report (PSUR).
- **Wave 3:** Risk Management Plan (RMP) and Risk minimization measures.
- **Wave 4:** Management and Reporting of Adverse Reactions to Medicinal Products.
- **Wave 5:** Post Authorization Safety Studies, Signal Management, Additional monitoring and Safety Communication.
- **Wave 6:** Pharmaco-epidimiology, Literature Review, Systematic Review and Meta-analysis, Study Designs, Evidence Based Medicine, statistics for Pharmaceutical Science.

- Design and Interpretation of Clinical Trials from Johns Hopkins University.
- Studying American board in clinical pharmacotherapy.

- **Finished my academic English courses in GUC :**

  - A.S (academic study skills)
  - C.S (critical thinking & scientific methodology)
  - CPS (communication skills & presentation)
  - RPW (research paper writing)

TRAINING EXPERIENCE

- **Certified Professional Trainer** Training by the American chamber of commerce in Egypt (Ongoing).
- **EARTH** 2018 Conference.
- ICH Good Clinical Practice by the Global Health Network.
- Egyptian Society of Pharmacology & Experimental Therapeutics **"ESPET"** first European-Egyptian Workshop on Pharmacovigilance in BUE.
- How to write and publish scientific Paper by TYT.
- National Hepatology & Tropical Medicine research institute "**NHTMRI**" Pearls conference.
- QPPV's Pharmaceutical Vigilance Training by Cairo Pharmacist Syndicate.
- Literature Citation Management Workshop by National Research Centre.
- Pharmacovigilance Awareness Training by Gerry Reed.
- Introduction to collecting Adverse Events by Global Health Training.
- Good Clinical Practice by NIDA Clinical Trial Network.
- Full summer internship 2013 in GSK quality control (raw material) (2 projects achieved).
- INTERNSHIP IN SANOFI.A PRODUCTION.
- Laboratory work shop in 57357 hospital.
- First aid workshop for 10 days in "Om El Masryen" hospital.
- Got an internship for two months in Dubai pharmacy**.**

WORK EXPERIENCE

DATACLin CRO
Pharmacovigilance Manager (QPPV)/Clinical Research Associate (CRA-2)
Mar-2018- Till Date

Achievements & Responsibilities as a Clinical Research Associate (CRA-1):
- Oncology Phase 4 Observational, Prospective, Cohort Study of 170 Patients in Egypt.
- Cardiology Phase 2 Interventional Study of 123 Patients in the National Research Centre in Egypt.
- Endocrinology Phase 2 Interventional Study of 185 Patients in Egypt.
- Rheumatology Phase 4 post marketing study of 400 patient in Egypt.

Achievements & Responsibilities as a Pharmacovigilance Manager (QPPV):
- Responsible of a team of 3 Pharmacovigilance Officers.
- Global Pharmacovigilance System Master File Preparation & Submission.
- Full Delegation for all Pharmacovigilance Activities for 4 Marketing Authorization Holder.
- Review of More than 3 Registration Packages Submission (>3 RMPs).
- Review of More than 10 Re-Registration packages Submission (> 10 ACOs, >10 RMPs).
- Review of More than 4 PBRERs and Waivers Submission following the EURD List.
- Pharmacovigilance Database System follow up (5 MAHs).

DATACLin CRO
Senior Pharmacovigilance officer Delegated as a PV Manager (QPPV)/Clinical Research Associate (CRA-1) **Aug-2017 –Mar-2018**
(7 Months)

Achievements & Responsibilities as a Senior Pharmacovigilance officer (QPPV) delegated as a PV manager:
- Responsible of a team of 3 Pharmacovigilance Officers.
- Full Delegation for all Pharmacovigilance Activities for 4 Marketing Authorization Holder.
- Pharmacovigilance Database System follow up (5 MAHs).

DATACLin CRO
Pharmacovigilance officer (QPPV)/Clinical Research Associate (CRA-1) Feb-2017—Aug-2017
(7 Months)

Achievements & Responsibilities as a Clinical Research Associate (CRA-1)
- NODCAR Package Submission for 4 different studies.
- MOH Follow up & Communication for 4 different studies.
- Principle investigators meeting for Protocol Development Discussion.

Achievements & Responsibilities as a Pharmacovigilance officer (QPPV)
- Full Delegation for all Pharmacovigilance Activities for 3 Marketing Authorization Holder.
- Pharmacovigilance Master file Preparation following the Saudi FDA.
- More than 5 Registration Packages Submission (>5 RMPs).
- More than 15 Re-Registeration packages Submission (> 15 ACOs, >15 RMPs).
- More than 10 PBRERs and Waviers Submission following the EURD List.
- Pharmacovigilance Database System follow up (5 MAHs).

DATACLin CRO

Pharmacovigilance officer (QPPV)/Clinical Trail Assistant (CTA) **Nov-2016—Feb-2017**

(4 Months)

Achievements & Responsibilities as a Clinical Trail Assistant (CTA)

- Ethics Committee Submission Packages Preparation for 3 different studies and 3 different sites (Ain Shams University, Cairo University & National Research Centre)
- 4 Ministry of Health Package Preparation for 4 Different Studies.
- 2 Trial Master Files Development.

Achievements & Responsibilities as a Pharmacovigilance officer (QPPV)

-Pharmacovigilance Focal Point for a T-MENA Region project (14 Countries).
- Pharmacovigilance Database System follow up (5 MAHs).
- Full Delegation for all Pharmacovigilance Activities for 1 Marketing Authorization Holder.
- More than 2 Registration Packages Submission.

DATACLin CRO

Pharmacovigilance officer (QPPV)/Medical Writer **Jul-2015—Nov-2016**

(> one year)

Achievements & Responsibilities as a Pharmacovigilance officer (QPPV)

- Pharmacovigilance System Master File Development and Submission to the Egyptian Pharmacovigilance Centre.
- Pharmacovigilance System Master File Checklist Development.
- Risk Management Plan Template Development.
- Periodic Benefit Risk Evaluation Report Template Development.
- Pharmacovigilance Database Communication and Settlement.

Achievements & Responsibilities as a Medical Writer

- Informed Consent Form Development following GCP.
- Attended >5 Advisory Boards.
- 2 Protocol Principle Investigator Discussion related to the following therapeutic areas (Cardiology, Rheumatology)
- 2 CSRs development.

DATACLin CRO

Data Administrator/ Pharmacovigilance Trainee **Mar-2015 – Jul-2015**

(4 Months)

Achievements & Responsibilities as a Data Administrator

- Four ongoing International Studies with the following Therapeutic Areas (Oncology, Rheumatology, Cardiology, & Diabetes).
- Four International Studies close out with the following Therapeutic Areas (2 Hypertension, Thrombosis & Diabetes).
- One International study Start up with Oncology Therapeutic Area.
- Query Resolution (>2000 query resolved).
- Database Validation.

Achievements as a Pharmacovigilance Trainee

-Practical Diploma and workshop in Pharmacovigilance given by Dr. Amr Saad (certified from Arab Union of the manufacturers of pharmaceuticals and medical appliances (AUPAM)(2015) details in Academic Achievements section.

United Health Care **17-Nov-2014 – 17-Mar-2015**

Medical representative (4 months)

- Worked as medical representative for 3 months in U.H.C on line Bio-dermis from Dec-2014 to Mar-2015.

EXTRA-CURRICULAR ACTIVITIES

- Member of SPSA clinic-ology team, GUC.
- Communication skill program by Track.
- Attended Basic Communication Skills course by Zidny.
- Got 1st place on Nasr city in intellectual Platform.

References will be provided upon request
