Marwa Mohamed Zaki



Date Of Birth: June 24 , 1984
Place Of Birth: Reyad , Saudi Arabia.
Gender: Female.
Nationality: Egyptian (Resident in Kuwait).
Marital Status: Married.
Address: Building 25 , 5 Street from Alblajat Street, Block3, Salmiya , Kuwait .

Contacts:

E-mail: marwazaki84@gmail.com
Mobile: +965/55018917

Objectives:

Utilizing and enhancing my skills & qualifications through a big organization which encourages continuous education and development of its employees, and through which I can interact and work efficiently in a dynamic environment to prove myself.

Education

- B. pharm degree , from faculty of pharmacy , Helwan University.
- Total Grade : Good
- Year Of Graduation : 2006.

Working Experience :

- **Regulatory Affairs Manager Health Planet Co. Kuwait**.
  Distributer for Glanbia, Solary, Bronsons, SAN, Optimum Nutration, Giant sport, Biobolics Nutration, MHP ,MuscleMeds, Muscle Sport, Isopure, Met RX , Sundown, Thompsons, Evolution ,Mr GUMMY, RenewLife, Nutrend, Dedicated , IRWIN, Redline, Biotech, VPX , NewChapter and Sports Research.

- **Head of Pharmacovigilance department and Pharmacovigilance trainer**
  Bahrain Pharma Egypt From 11/2017 till 4/2018.

- **Regulatory Affairs Associate and QPPV (Qualified Person for Pharmacovigilance) and drug Saftey Responsible**
  Bahrain Pharma Egypt from 8/2016 till 10/2017.

- **Regulatory Affairs Specialist** and **QPPV backup**
  Pharmacovigilance and Drug Registration Training Center (PDRC) from 5/2016 till 8/2016.

- **Hospital Pharmacist** At: Matareya Teaching Hospital (MTH) from 5/2007 to 5/2009

- **Community Pharmacists**
  from 9/2006 to 4/2016

Qualifications

- Responsible for all tasks associated with Artwork creation and maintenance for product in the Egyptian markets in addition to providing support to the local regulatory affairs staff with other regulatory activities.
- extensive knowledge of Pharmacovigilance regulations and have strong leadership, communication, and problem-solving skills, along with a demonstrated ability to build and manage close relationships with colleagues in businesses. Experience interacting with auditors / inspectors and conducting qualification audits is a plus.

Major Activities and Responsibilities

- Preparation of new labels and artworks for products within agreed timeline.
- Understand the local / regional regulatory guidelines and requirements for specified product line(s).
- Updating current labels to match reference markets documents within agreed timeline.
- Responsible for artwork text translation either internally or to coordinate via 3rd party vendor. Responsibility includes getting quotation, following its approval, communicating approval to vendor and getting translated text on agreed timeline
- Follow up with Corporate Editing group or 3rd Party vendor to develop agreed artwork within specific timeline.
- Identifying labeling issues as: errors, inconsistencies, conflicts, etc., between package leaflet text statements and reference documents. Acting decisively to solve such issues.
- Preparation of artwork comparison table for Regulatory Team Review and submission purposes.

Additional responsibilities include :

- Maintains product and facility licenses, ensuring they are up-to-date and compliant with applicable regulations and guidance
- Communicate with the distributors in each of the markets to ensure optimized and compliant Registration procedures.
- Effective communication to key stakeholders of key issues that could impact regulatory strategies or the business.

- Ensure proper archiving for all related document.
- General customer services activities, responding to miscellaneous queries, requests for data, declarations, etc.
- Verify accuracy of information loaded into an electronic system in comparison with local/BoH records.
  - Responsible for ensuring training and development is disseminated throughout PV Personal. This is achieved by working with PV teams to ensure there is a compliant training plan in place.
  - Responsible for identifying any PV skills, knowledge or resource gaps and proposing solutions to correct any defecits.
  - Responsible for ensuring compliance with MOH policies and procedures in relation to PV.
  - Responsible for assisting markets in preparation and response to formal audits.

Functional competencies:

PV Intelligence

- knowledge of pharmacovigilance systems & requirements

- knowledge of pharmacovigilance principles, concepts, practices & standards

- in depth knowledge of the local country(ies) pharmacovigilance regulations & obligations

- understanding of risk management

- Knowledge local country(ies) industry code(s) of practice

People Management

- ability to identify talent and develop direct reports

- ability to coach and motivate those undertaking PV activities

- ability to manage performance of direct reports

TRAINING EXPERIENCE, SUMMER COURSES & EDUCATION

A- Certified From Arab Leagues Union and from Arab Union of the manufacturers of Pharmaceuticals and medical appliance

1- A QPPV Training on Pharmacovigilance systems and their quality systems, Pharmacovigilance Master File (PSMF),Pharmacovigilance inspections&Pharmacovigilance Audits

2- A QPPV Training on Management and Reporting of

Adverse reactions to medicinal products

3- A QPPV Training o Risk Management Systems and Risk Minimization measures: selection of tools and effectiveness indicators

4- A QPPV Training on Periodic Benefit- Risk Evaluation Report (BEBRER)

5-A QPPV Training on Post authorization Safty studies, Signal Management Additional Monitoring and Safty Communication

6- A QPPV Training on Pharmacoepidemiology, & Evidence based Medicine , Appropriate literature review, Systemic review of meta-Analysis ,Evidence based medicine in Pharmacy Practice , Study designs ,Essential Statistics for the Pharmaceutical sciences

7- A QPPV workshop on Medical Aspects of Adverse drug reactions (ADRs),

Case narrative writing and ideal processing of Individual case safety reports (ICSRs)

8- Pharmacovigilance training Practical workshop on Pharmacovigilance system master file (PSMF), Periodic Saftey update Report (PSUR) And Risk management Plan (RMP).

B- RMP Training Course from Parmacovigilance and drug Registration Training Center 5/2016.

C- Regulatory Affairs Training Course From BAXTER Healthcare and Medical devices at 5/2016.

D- Training at Sanofi Aventis Company as Sales Rep from 6/2005 till 8/2005.

E- Training at El Ezaby Pharmacy from 9/2006 to 12/2006.

Skills:

Computer Skills:

- Excellent in long word processing, presentation & spreadsheet application skills

- proficient in use of a safety database

- ability to learn new computer interface systems

- Good Knowledge of Microsoft Office Applications (Excel, PowerPoint, Access, Outlook, Project).

- Excellent Knowledge of Windows XP , Windows 7 & windows 8.

- Excellent Knowledge of Internet Explorer.

Communication skills

- excellent written & good spoken English

- good presentation skills

- ability to communicate effectively verbally and in writing

- Native Arabic Language.

- proficient in Good Documentation Practices

Personal Skills:

- Strong project management skills with the ability to prioritise assignments

- Excellent time management, organizational & planning skills

- High level of accuracy & quality in work

- Strong collaboration skills with the ability to work across boundaries

- Strong problem solving capability

- Sense of urgency and the ability to make rapid, disciplined decisions

- Good training skills

- Strong leadership and interpersonal skills
- Compliance mindset/focused
- Courage and candor

References:

Available upon request.