Pharmacovigilance in Middle East Conference

20-21 January, 2012 Yas Rotana Hotel Abu Dhabi UAE

HAAD Accredited for “7.25” CME Hours

❖ Target Audience:

- Regulatory Authorities; (Safety Programs, Regulatory affairs)
- Pharmacovigilance Solution/Systems/Technology Providers.
- Risk Management Consultants.
- Pharmaceutical Companies, CROs and Consultancy Firms (Drug safety, Regulatory affairs, Medical affairs, Quality assurance, Safety process, Post-marketing surveillance, Signal detection, Patient safety, Data management, R&D)
- Personnel for: (Pharmacovigilance, Medical monitoring, Drug safety project manager, Safety and risk management, Community Pharmacists, Clinical Pharmacists, Physicians)

1st Day of the Conference; 20th January, 2012

7:30am - 8:30am Registration

8:30am - 9:00am HAAD Opening Remarks

Dr. Mohammed Abuelkhair
Head, Drug and Medical Product Regulation Section
Health Authority-Abu Dhabi

9:00am - 9:30am Federal Pharmacovigilance Committee Speech “Pharmacovigilance System in UAE”.

Dr. Amin Alameeri
Asst. Undersecretary for Medical Practice and License (CEO)
Ministry of Health, UAE
9:30am – 10:00am  Current Practice of PV in Abu Dhabi.  

*Dr. Mohammed Abuelkhair*  
*Head, Drug and Medical Product Regulation Section*  
*Health Authority-Abu Dhabi*

10:00am -10:30am  Spontaneous reporting: Saudi Arabia Experience

10:30am -11:00am  Expedited Reporting: Regulatory Perspective

- Definitions: ADEs, Serious events, unexpected events and serious Unexpected events.  
- Backbone structure of ICSRs  
- New Pharmacovigilance legislations

*Dr. Nasser AlQahtani*  
*Head, ADRs Evaluation Division*  
*Saudi Food and Drug Authority (SFDA)*

11:00am -11:30am  Break

11:30am -12:00 pm  Periodic Safety Update Reports (PSUR)

- What is a PSUR  
- Regulatory requirements for PSURs (International and in MENA)  
- Differences in PSURs for Originators Vs Generics  
- How to prepare a PSUR

*Dr. Lubna Rshaidat*  
*Regulatory Affairs Department Head*  
*Tabuk Pharmaceuticals-Jordan*

12:00pm-01:45pm  Friday Prayer & Lunch

01:45pm-02:30pm  Risk management plans in PV

- To differentiate between risk management plans and risk minimization plans  
- To outline the structure of RMP  
- To have a background about the international requirements

*Dr. Adel Alrwisan*  
*Vigilance and Crisis Management Executive Directorate*  
*Saudi FDA*
02:30pm-03:15pm  Global Networking in Pharmacovigilance.

- Progress in the PV scope
- Global system in PV
- Signal detection

Dr. Amr Saad  
Head of the Egyptian pharmacovigilance Center  
EPVC

03:15pm-04:00pm  Information Technology Systems in Pharmacovigilance.

Mr. Subbaraju Sagi  
Managing Director  
Life & Health Sciences, TechSol

&  
Robbert P. van Manen, M.Sc.  
Master Principal Sales Consultant  
Oracle Health Sciences

04:00pm-05:20pm  Reporting Pharmacovigilance Profiles of different Medications (Workshop)

- Approved REMS plan for (Sitagliptin/metformin) Combination

Bernd Voss  
Regional Director of Medical Affairs for Diabetes (Eastern Europe, Middle East, Africa)  
MSD RBSC in Munich, Germany

05:20pm-05:30pm  Closing Remarks.

End of the first day of the conference
2nd Day of the Conference; 21st January, 2012

08:00am-08:15am  Opening the Second Day of the conference

08:15am-09:00am  Training plans for PV Personnel
- Who can be a QPPV.
- What are the responsibilities of a QPPV.
- International Qualifying Training Courses.

Dr. Mohammed Saleem
Managing Director of SIPS
SIPS, Jordan

09:00am-09:40 am  Medication Errors Reporting
- Define and categorize a medication error
- Report medication errors
- Investigate medication errors

Dr. Adeline Saliba
Acting Pharmacy Manager/Medication Safety Manager
Al corniche Hospital

09:40am-10:00 am  Assessing your medication management system
- Benefits of assessing
- Recommended tools to assess your medication management system
- Developing action plans relevant to your assessment and defining priorities

Dr. Lana Hammad
Head of Pharmacy Department
Al Rahba Hospital

10:00am-11:20 am  Reporting Pharmacovigilance Profiles of different Medications
(Workshop)
- Romiplostim - Modified Nplate REMS program

Dr. Tamer Saad
Medical Director
Amgen MEA

- Efficacy and safety of Dusasteride on management of benign prostatic hyperplasia
Dr. Essam Fikry  
Senior Medical Affairs Manager for Oncology and Urology  
GSK

11:20am-11:50am  Break
11:50pm-01:50pm  Developing Key Performance Indicators (Workshop)

• Should Key Performance Indicators for Clinical Services Be Mandatory
• Describe how to identify and select Key Performance Indicators (KPIs) that align with organizational needs
• Identifying your targets
• Define challenges in meeting your target

Dr. Lana Hammad  
Head of Pharmacy Department  
Al Rahba Hospital

01:50pm-02:00pm  Closing Remarks.

Lunch

End of the Second Day of the Conference