



**Under the Patronage  
of Her Royal Highness Princess  
Sumaya Bint El Hassan**



**Track & Trace System**



- Securing IDs
- Anti-Counterfeiting
- Secure Point-Of-Sale Information

## First MENA Pharmaceutical Track & Trace Conference

17<sup>th</sup> - 18<sup>th</sup> June, 2014  
Le Meridien  
Amman-Jordan

### Background

Globalization of the pharmaceutical industry presents a regulatory challenge the health regulatory authorities must address to ensure the safety and quality of drug supply chain. Because of this increasing globalization, substandard, falsified, and counterfeit (SFC) drugs present serious threats to global product safety and integrity. Instituting a robust track and trace system for each step of the supply chain would improve the safety and security of the drug supply chain by preventing the introduction of SFC drugs.

In participation with



This conference will focus on bringing a common understanding of what track and trace system is and how it can help assuring the supply chain safety. Regulatory authorities work with manufacturers and other supply chain partners is necessary to successes in implementing such system. The conference program is comprised of two days; the second day will be dedicated to steering committee meetings.



### Objectives

- Identify the main pillars that help ensure the safety and quality of the drug supply chain.
- Recognize international initiatives to implement track and trace system in order to safeguard the global supply chain.
- Present examples of regional Track and Trace Systems (focusing on the successful Turkish experience).
- Highlight the necessity for an international tracking system.
- Initiate a steering committee to work on harmonization of an international tracking system in the region.

### Who Can Attend?

- International and National Regulatory Authorities
- National and International Pharmaceutical Industries
- Regulatory Affairs Experts and Consultants
- Pharmaceutical Distributors and Retailers
- Interested Healthcare Professoio

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Exhibitors



## First MENA Track & Trace Conference Under the Patronage of HRH Princess Sumaya Bint El Hassan 17<sup>th</sup> - 18<sup>th</sup> June 2014

### Day One

- 08:15-08:45 Registration
- 09:00- 09:30 Opening Ceremony under the Patronage of Her Royal Highness Princess Sumaya Bint El Hassan.
- Apex Welcoming Note
  - H.E Layla Najem - Minister Plenipotentiary – Chairperson of the Committee on Health and Humanitarian Aid (TBC)
  - H.E. Dr Hayel Obidate, Director General of JFDA
- 09:30-10:00 Exhibition Opening by Her Royal Highness Princess Sumaya Bint El Hassan  
Cocktail Reception
- 10:00-10:15 Conference Overview and Objectives – Dr. Hanan Kakish, Regional Technical and Innovation Director at Apex, Former Medical Research Scientist at U.S. FDA, MENA Office.

### Session One: International Initiatives and Implementation Mile Stones

- Chaired By:** H.E Ambassador Joanna Wroncka Head of EU Delegation to Jordan  
**Moderated By:**
- 10:30-11:00 **WHO Perspective** for the Substandard/Spurious/ Falsely Labeled/ Falsified/Counterfeit (SSFFC) Medical Products – Dr Mohamed Ramzy Ismail, WHO EMRO Representative.
- 11:05-11:20 **IPR and the Fight against Counterfeit Medicines** - Brian Grimm, Economic Consuldar, U.S. Embassy
- 11:25-11:55 **The U.S. FDA's Efforts to Safeguard the Global Supply Chain** Emphasizing on the Drug Quality and Safety Act Signed Last November- U.S.FDA Representative
- 12:00-12:35 **The European Approach to Traceability and Governance and The EU Falsified Medicine Directive** – Dr. Francois-Xavier LERY, Head of Section for Pharmaceutical Care, Consumer Health Protection and Anti-Counterfeiting- European Directorate for the Quality of Medicines & HealthCare (EDQM)
- 12:35-13:05 **USP chapter <1083> Good Distribution Practices focusing on Supply Chain Integrity and Security** and How It Is Linked to The New Drug Quality and Safety Act- Dr. Mary Foster, Chair of the Packaging, Storage and Distribution Committee.
- 13:05-13:20 Questions and Answers  
Closing by the moderator
- 13:20-14:20 Lunch Break

### Session Two: Track and Trace Requirements in the Arab World and Future Polices

- Chaired By:** H.E. Dr. Raed Hijazeen – Head of Health and Environment Committee, Jordanian Parliament  
**Moderated By:** Dr. Hakima Hoseh - Compliance Regulatory Affairs Sr. Manager, Hikma Pharmaceuticals PLC

- 14:20-14:50 **Saudi FDA Perspective** -Dr. Abdullah Fahed Almeshal, Manager of Technology Management Department, Drug Sector at SFDA
- 14:55-15:20 **League of Arab State Strategy and Implementation** – Dr Lubna Rshaidat, Member in the "Highest Technical Committee for Arab Medicines" – Arab league/Council of Arab Health Ministers.
- 15:25-15:50 **GS1 Standards for Healthcare**- Maysaloun (May) Gammouh, Director General of GS1 Jordan
- 15:55-16:10 **Jordan FDA Current and Future Implementation** – Amal Abu Al Rob, Pricing Department at JFDA.
- 16:10-16:30 Questions and Answers  
Closing by the Moderator

### Day Two

#### Session Three: Case Studies Pros and Cons

- Chaired By:** Eng. Lina Owis - Deputy General Director- The Jordanian Pharmaceutical Manufacturing Company  
**Moderated By:** Dr. Ikhlas Al Hadidi - Director of Drug Directorate at JFDA  
**Co-Moderated:** Mr. Mohamed Odeh Head of Analysis and Programming Department at JFDA
- 09:00-09:30 **Turkish Implementation**-Vice President of the Turkish Medicines and Medical Devices Agency Dr Hakkı GURSOZ  
Track and Trace System Implementation in Turkey- Mr. Taha Yayci, Consultant at Turkish Medicines and Medical Devices Agency.
- 09:30-09:40 **Track and Trace System future aspects** in connecting with patient electronic information for establishing electronic pharmacovigilance data base- Mr. Taha Yayci.
- 09:40-09:50 **Current Status of Turkish Pharmaceutical Track & Trace System** –Mr. Okan KOYLU, Project Manager of Turkish Pharmaceutical Track & Trace System, Tigo Information Technologies
- 09:50-10:20 **Need and Essentials for Implementation of Track and Trace System** – Mr. Harpal Singh, Director Business Development, ACG Inspection Systems
- 10:20-10:35 Mettler Toledo Representative
- 10:40-11:15 Questions and Answers  
Closing by the Moderator
- 11:15-11:30 Coffee Break
- 11:30-13:30 **Road Mapping and Futuristic Output-Session 1**
- 13:30-14:30 Lunch Break
- 14:30-16:15 **Road Mapping and Futuristic Output-Session 2**
- 16:15 -16:30 Coffee Break
- 16:30 - 17:00 Closing and Outcomes