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## **Customer Event Cairo**

18 April 2024

## <u>Agenda</u>

08:00-09:00 . . . Sign in and welcome

## 09:00-09:30 . . . Keynotes

- Dr. Venkat Surendra Nath Koduru USP Senior Vice President, Regions & Program Operations (10')
- Dr. Ali El-Ghamrawy Chairman of the Egyptian Drug Authority (10')
- Dr. Aiman El-Khateeb Vice Chairman of the Egyptian Drug Authority (5')
- Dr. Alessandro Slama Vice President RPO, GM USP Switzerland, USP-EMEA (5')
- Dr. Gamal El-Leithy Chairman of Chamber of Pharmaceutical Industries, Cosmetics and Medical Supplies (5')

09:30-11:30 . . . Session 1: Risk mitigation to Pharmaceutical Quality - the Role of Reference Standards

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Time	Topic	Speaker
09:30 – 10:30	How to reduce potential risk of noncompliance: regulations and quality standards – Q&A included	Dr. Christian Zeine (USP Sr. Scientific Affairs Mngr. EMEA)
10:30 – 10:55	EDA-USP Collaboration and activities	Dr. Mohamed Abdallah (CADC Head, EDA)
10:55 – 11:20	Egyptian pharmacopeia strategic alliances: maximizing manufacturers' benefits through adopted agreements	Dr. Lobna Sallam (EDA)
11:20 – 11:50	Break	
11:50 – 12:30	Panel Discussion Unlocking Success: How pharmacopeial standards empower generic manufacturers?	Dr. Christian Zeine (Sr. Scientific Affairs Manager EMEA), Dr. Zakiya Al-Kurdi (USP GEA-EMEA Director) Dr. Mohamed Abdullah (CADC Head, EDA), Dr. Asmaa Fouad (BioInn Head, EDA)

12:30-16:30 . . . Session 2: Impurity testing the need and challenges: How far should we go?

Time	Topic	Speaker
12:30 – 13:05	USP's perspective on impurities: needs, challenges - and solutions in your lab's daily work	Dr. Christian Zeine (Sr. Scientific Affairs Manager EMEA)
13:05 – 13:30	USP General Chapter <467> RESIDUAL SOLVENTS: an overview	Dr. Christian Zeine (Sr. Scientific Affairs Manager EMEA)
13:30 - 14:30	Lunch	
14:30 – 15:10	Mastering impurity testing: method development, validation, and verification to help overcome challenges in registration process	Dr. Amanda Guiraldelli (USP Scientific Affairs Manager EMEA) and Dr. Christian Zeine (USP Sr. Scientific Affairs Manager EMEA)
15:10 – 15:40	What drives the risk of out-of-specifications results and batch failure? – case studies	EDA Representative
15:40 – 16:20	Improving Public Safety Using Risk-Based Post- Marketing Surveillance	Victor S. Pribluda (USP Sr. International Regulatory Manager) Dr. Salah Allam (EDA)

16:20-16:30 . . . Closing Remarks

Moderated by: Dr. Alessandro Slama, Vice President RPO, GM USP Switzerland, USP-EMEA

## <u>Venue</u>

The forum will be held at the Renaissance Cairo Mirage City Hotel, Abbas Al Akkad Corridor, Mirage City, New Cairo, Egypt