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A legacy of trust brings confidence in quality medicine for patients

14 October 2024

Agenda

08:00–09:00 . . . Welcome and Sign in

09:00–09:30 . . . Keynotes

- Dr. Zakiya Al-Kurdi – USP Regional Manager MEA and GEA-EMEA Director (5')
- Dr. Alessandro Slama – Vice President Regions RPO and General Manager USP Switzerland, EMEA (5')
- Dr. Nizar Mahmoud Mhaidat – Jordanian FDA Director General (10')
- Dr. Hanan Sboul – Chairperson of USP MENA Regional Chapter (10')

09:30–11:45 . . . Session 1: Risk mitigation to Pharmaceutical Quality - the Role of Reference Standards

Time	Topic	Speaker
09:30 – 10:00	Introduction to USP and what are the new updates in USP-NF	Dr. Sara N. Elhelaly (Strategic Customer Development Manager)
10:00 – 10:30	The role of reference standards in ensuring quality of medicines and understanding risks	Dr. Christian Zeine (Sr. Scientific Affairs Manager EMEA)
10:30 – 10:45	Update requirement for reference standards at DQCL at JFDA	Dr Rima Saleh – (JFDA)
10:45 – 11:15	How to Mitigate Risks to Pharmaceutical Quality: Case studies	Dr. Christian Zeine (Sr. Scientific Affairs Manager EMEA)
11:15 – 11:45	Panel Discussion	

11:45–12:15 . . . Break

12:15–14:30 . . . Session 2: Pharmaceutical Testing and Compliance: USP's and JFDA Evolving Framework

Time	Topic	Speaker
12:15 – 12:45	New USP General Chapter <477> User Determined Reporting Thresholds: What are the implications for USP users and how does it align with current ICH impurity guidelines Q3A/B?	Dr. Christian Zeine (Sr. Scientific Affairs Manager EMEA)
12:45 – 13:05	Impurities and reporting threshold ICH guidelines adherence	Rand Farag (JFDA)
13:05 – 13:35	EG/DEG testing of High-Risk Excipients: How USP's efforts will help you be more confident in ensuring the safety and quality of your pharmaceutical products	Dr. Christian Zeine (Sr. Scientific Affairs Manager EMEA)
13:35 – 13:55	Nitrosamine & EG/DEG impurities in API: Risk assessment, evaluation, and specification limit	Yaman Hamad (JFDA)
13:55 – 14:15	Health hazard evaluation committee measures to handle EG/DEG impurities in pharmaceutical products	Gabr Gabr (JFDA)
14:15 – 14:30	Panel Discussion	

14:30–14:40 . . . Closing Remarks - Dr. Zakiya Al-Kurdi – USP Regional Manager MEA and GEA-EMEA Director (10')

14:40–15:40 . . . Lunch

Venue

The event will be held at the Hilton Amman, Elia Abu Madi St. Shmesani, Amman, Jordan