

Meet. Connect. Discover.

Agenda Cairo, 8 March 2023

- 8:00AM – 9:00AM Sign in and welcome coffee
9:00AM – 12:30PM Seminar (Plenary session)
12:30PM – 1:30PM Lunch
1:30PM – 3:15PM Workshops (Group split in 2 Break-out sessions)
3:30PM – 4:00PM Seminar (Plenary Session)

Seminar 9:00AM – 12:30PM

- Welcome
 - Dr Alessandro Slama, General Manager, USP EMEA
 - Dr Tamer Essam, President, Egyptian Drug Authority
 - Dr Gamal El-Leithy, Chairman, Industrial Chamber of P.C.A
- “Egyptian Pharmacopeia / Work of EDA for supporting Quality of Medicines in Egypt” presented by Egyptian Drug Authority (20min)
- “Aiming to increase exportation of Pharma Industry” by Indus Chamber of PCA (20min)
- General Overview of the USP
- Reference standards

Afternoon workshops 1:30PM – 3:15PM (Each attendee to select his/her workshop of choice)

Workshop 1: Impurities in Small Molecules Medicines: Nitrosamines Impurities

- Nitrosamines: Regulatory landscape, USP tools and paper on complex Nitrosamines
 - Case study on Risk assessment followed by group discussion/USP
- Introduction to Pharmaceutical Analytical Impurities
 - Case study on “challenges during Impurity testing” followed by group discussion/EDA

Workshop 2: Transfer, Validation, Verification: Current situation and evolution

- Existing General chapters <1224>, <1225> <1226>
 - Case study on “challenges during tech transfer” followed by group discussion
- Future of validation concept ICHQ14, focus on ICH Q2R2
- Introduction to General Chapter <1220> Analytical Procedure Life Cycle

Seminar 3:30PM - 4:00PM

- “Post Marketing Surveillance” presented by Egyptian Drug Authority (20 min)
- Wrap-up and Adjourn

Venue

The forum will be held at the **Renaissance Cairo Mirage City Hotel:**
Abbas Al Akkad Corridor, Mirage City, New Cairo, Cairo 11757, Egypt