

Meet. Connect. Discover.

User Forum Istanbul

18 October 2022

Agenda

09:00–10:00 Sign in and welcome coffee 10:00–12:30 Seminar

- USP Overview
- Regional Chapter overview
- Pharmaceutical Analytical Impurities
- Biotechnology
- Nitrosamines

12:30–13:30 Lunch 13:30–15:00 Workshops 15:00–16:00 Summary

The afternoon workshops session will consist of three groups:

Group A: Chemical

- Impurity testing general overview
- Nitrosamines

Discussion topics:

- How pharma's develop/execute their testing
- What PAIs are used (groups such as starting materials, intermediates, by-products, degradants)
- Case studies

Group B: Biotechnology

- Analytical test considerations for biosimilars
- Impurity analysis
- Emerging technologies (MAM, AQbD)

Discussion topics:

- Bio-Pharma's experiences / Case studies
- Insights and suggestions on where standards can help

Group C: Regulators / Academia

- USP Convention
- Resolution and engagement activities

Discussion topics:

- Supply Chain (TITCK new Guideline for Counterfeit)
- Post Marketing Surveillance Activities

Venue

The forum will be held at the Marriott Sisli: Merkez, Abide-i Hürriyet Cd 142 Şişli, Istanbul 34381, Turkey