Pharmaceuticals Interest Group Workshop at the 73rd ASMS (Baltimore, MD)

Title of the workshop: Nitrosamine Analysis: Evolving Challenges and Emerging Solutions

Date of the Workshop: Monday, June 2nd, 2025

Organizers/Presiders list: Paolo Lecchi (United States Pharmacopeia), Jessica Hoskins (AbbeVie), Valeria Guidolin (Pfizer) and Mack Shih (FDA) [not present at the workshop].

Attendance: ~80 people

Nitrosamines remain a persistent challenge for the pharmaceutical industry, and ongoing scientific advancements continue to drive the need for reliable and sensitive analytical strategies.

The objective of the workshop was to provide updates and foster open discussion on recent developments in the analysis of nitrosamines and NDSRIs in pharmaceutical preparations.

Following a brief introduction and opening remarks outlining the objectives of the workshop, the program featured four presentations:

- Andrew Leightner - Waters, Milford (MA). “The Nitrosamine Evolving Challenge and Exigent Solution”
- Sourya Assaf - US Pharmacopeia, Rockville (MD). “USP Resources for Nitrosamines”
- Tucker Kitchengs - Syft Technologies, Pittsburgh (PA). “High-Throughput Nitrosamine Analysis Using Headspace-SIFT-MS”
- Dande Aishwarya, National Institute of Pharmaceutical Education and Research (NIPER), Hajipur, (India). “LC-Q-Orbitrap-HRMS Method for NDMA Determination and Genotoxic Nitrosamine Mitigation in Metformin Hydrochloride Drug Products”

The four speakers each represented a different organization, collectively covering a broad spectrum related to nitrosamine. They brought unique perspectives on ongoing issues, discussed new and emerging analytical methods, and highlighted the specific roles their organizations play in addressing the topic. The workshop was well attended with lively discussions between attendees and panelists.

In addition to the presentations and discussions, live polls were conducted throughout the workshop, which concluded with a well-received nitrosamine quiz competition.

The absence of representatives from federal agencies, particularly the Food and Drug Administration, had an impact on the scope of the workshop discussions, as it limited the opportunity to include direct updates on regulatory perspectives and ongoing initiatives relevant to the topic. While these contributions had been anticipated as part of the planned agenda, their absence understandably resulted in a somewhat narrower discussion in that area. Nonetheless, the workshop remained productive and engaging, thanks to several speakers and panelists who adjusted their contributions or stepped in on short notice to help maintain the relevance and continuity of the session.

Additionally, we are appreciative of the A/V staff at the Baltimore Convention Center for their technical support before the workshop.