

Joint Meeting of the Generic Medicines and Excipients Sectors and European Chapter  
of the USP Convention:

Discussions on new guidances for nitrosamines: US, Canada, and Europe  
Thursday, September 21, 9:00-10:30am ET

1. Chairs' introductory remarks

- David Gaugh, R.Ph., Chair, Generic Medicines Sector, and Interim CEO, Association for Accessible Medicines (AAM),
- Erik Burns, Ed.D., M.B.A., Chair, Excipients Sector, and Senior Director of Corporate Engagement and Strategic Business Initiatives, American Association of Pharmaceutical Scientists (AAPS)
- Catherine Duggan, Ph.D., Chair, European Chapter, and CEO, International Pharmaceutical Federation (FIP)

2. Update on USP's global engagement on nitrosamines, Mrunal Jaywant, Ph.D., Vice President, Research and Development, Science (USP)

3. Panel Discussion and Q&A, moderated by Mrunal Jaywant

Recent guidance published by regulating agencies (FDA, Health Canada, and EMA) is directing/signaling industry on the approach to mitigate patient risk in light of nitrosamine contamination discoveries. This panel will explore the guidances' commonalities, distinctions, and expected impact on patient safety.

- [Giuseppe Randazzo](#), M.S., Vice President, Sciences and Regulatory Affairs, Association for Accessible Medicines
- [Kristin Willemsen](#), M.S., Vice President, Scientific & Regulatory Affairs, Canadian Generic Pharmaceutical Association
- [Valerie Niddam-Hildesheim](#), Ph.D., Chair, Nitrosamines Working Group, Medicines For Europe; and Senior Director, Global Nitrosamines Project Lead, Teva Pharmaceuticals

4. Convention Member Reflections

Open portion whereby Members discuss their nitrosamine challenges, how the recent guidances have affected their organizations, and efforts with connecting with peers around the globe to share information on nitrosamine risk mitigation strategies.

5. Closing Remarks, above Chairs