USP workshop on 'Excipient composition and organic impurities'

Agenda (Dates: 15-16 September 2021)

DAY ONE: Collaborating with USP on excipient standards setting activities with a focus on USP's published stimuli article on complexities in setting excipient compendial specifications for composition and organic impurities		
Indian Standard Time	Eastern Standard Time	Topic
5:00 p.m.	7:30 a.m.	**Welcome remarks and Goals and deliverables of the workshop** Mr. Sudarshan Jain, Secretary General, IPA Dr. Catherine Sheehan, Senior Director, Science-Excipients, USP and Dr. Mrunal Jaywant, Senior Director, R&D, USP India
5:10 p.m.	7:40 a.m.	**Keynote address** Dr. Otilia Koo, Director, Integrated Development Teams, Bristol-Myers Squibb | Chair, USP Complex Excipients Expert Committee (EC)
5:15 p.m.	7:45 a.m.	**Steps for stakeholders to engage with USP on excipient standard setting activities** Dr. Catherine Sheehan, USP and Chuck Bates, Consultant, USP
5:35 p.m.	8:05 a.m.	**Historical and Current Overview of USP-NF Excipient Monograph Composition and Impurity Revisions** Dr. Hong Wang, Senior Manager, USP
5:55 p.m.	8:25 a.m.	**Setting POLYMERIC excipient specifications: consideration of solvents and monomers** Dr. Johanna Eisele, Head, Regulatory Affairs, Evonik
6:10 p.m.	8:40 a.m.	**Excipient composition and organic impurities – USP prospective and engaging stakeholders** • Overview of Guiding Principles and Approaches for Setting Specifications for Excipient Composition and Impurities • USP Review of Stimuli Article's Proposed Definitions relating to Excipient Composition and Impurities Dr. Galina Holloway, Senior Scientific Liaison, USP
6:30 p.m.	9:00 a.m.	**Q&A session and closing**
7:15 p.m.	9:45 a.m.	**Adjourn**

DAY TWO: 'Excipient composition and impurities': Industry challenges with impurities in Excipients.		
Indian Standard Time	Eastern Standard Time	Topic
5:00 p.m.	7:30 a.m.	Industry perspective (Drug product) on control strategies for organic impurities in excipients Dr. Sumedha Nadkar, Site Head and Senior Director, Consumer Healthcare R&D at Perrigo India
5:30 p.m.	8:00 a.m.	PANEL DISCUSSION 1 The importance of understanding the impact of variability in excipient quality and performance Moderators: Dr. Brian Carlin, Director, QbD/Regulatory, DFE Pharma | Member, USP Excipients Test Methods (ETM) Expert Committee (EC) and Dr. Catherine Sheehan, USP Speaker: Dr. Shaukat Ali, Technical Support Manager, BASF| Member, USP ETM EC Panelists: • Dr. Shaukat Ali, BASF • Dr. Dirk Leutner, Head, Pharmaceutical Technology Section, European Pharmacopoeia, EDQM • Dr. Otilia Koo, Bristol-Myers Squibb | Chair, Complex Excipients EC, USP • Dr. Vipul Doshi, Chief Quality and Compliance Officer, Zydus Cadila • Dr. Chris Moreton, VP, Pharmaceutical Sciences, FinnBrit Consulting | Chair, USP ETM EC • Dr. Sumedha Nadkar, Site Head and Senior Director, Consumer Healthcare R&D at Perrigo India • Dr. Hong Wang, USP
6:00 p.m.	8:30 a.m.	**Results from USP's survey on Nitrosamines in Excipients** and USP's Nitrosamines exchange Dr. Mrunal Jaywant, USP and Naiffer Romero, Sr. Manager, Scientific Affairs, USP
6:15 p.m.	8:45 a.m.	PANEL DISCUSSION 2 **Industry challenges with sources of Nitrosamines in Excipients** Moderator: Dr. Mrunal Jaywant, USP Speaker: Dr. Fan Wu, Technical Director of Global Measurement Science, Ashland LLC | Member, USP Complex Excipients EC Panelists: • Dr. Fan Wu, Ashland LLC

		• Dr. Sushil Jaiswal, Executive Director-Global Quality & Regulatory Affairs, Torrent Pharmaceuticals Limited • Dr. Shaukat Ali, BASF • Dr. Pritesh Upadhyay, SVP, R&D, Lupin Limited • Dr. Jin Zhao, Principal Investigator, Pharma Solutions, International Flavors and Fragrances | Member, USP Complex Excipients EC • Dr. Catherine Sheehan, USP/Dr. Galina Holloway, USP
6:45 p.m.	9:15 a.m.	**Next Steps:** Dr. Catherine Sheehan, USP
6:55 p.m.	9:25 a.m.	**Closing Remarks:** Mr. Shirish Belapure, Technical Advisor, IPA