Agenda, Updated on May 24, 2022

AGENDA
USP Workshop: Control of Nitrosamine and Other Mutagenic Impurities in Human Drugs
人用药中亚硝胺及基因毒性杂质控制研讨会
May 27, 2022 CST (Shanghai, China)

Zoom Event English-Chinese simultaneous translation		
Control of Nitrosamine and Other Mutagenic Impurities in Human Drugs **人用药中亚硝胺及基因毒性杂质控制研讨会**		
8:30 a.m. – 11:40 a.m.	Morning Session Moderator: Dr. Xiao Ling, USP	
	8:30 – 8:50 a.m. (8:30-8:50 pm EDT, May 26th)	Welcome Address 开幕致辞 • Dr. Ed Gump, Vice President, Small Molecules, USP • Dr. Jeff Moore, Senior Director, Scientific Affairs & Strategy, USP
	8:50 – 9:30 a.m. (8:50-9:30 pm EDT, May 26th)	Control of Nitrosamine Impurities in Human Drugs 人用药中亚硝胺杂质的控制 • Dr. Jason Rodriguez, Director, CDER/OPQ/OTR/DCDA, FDA
	9:30 – 10:10 a.m. (9:30-10:10 pm EDT, May 26th)	Highlights and key points of USP <1469> Nitrosamine Impurities USP <1469> 亚硝胺杂质通则要点 • Dr. Edmond Biba, Principal Scientist, General Chapters, USP
	10:10 – 10:40 a.m. (10:10-10:40 pm EDT, May 26th)	Nitrosamine Impurities – The compendial Response & Resources 亚硝胺杂质 – 药典的应对及资源 • Mr. Naiffer Romero, Senior Scientific Affairs Manager, USP
	10:40 – 11:10 a.m. (10:40-11:10 pm EDT, May 26th)	Industry challenges with sources of Nitrosamines in Excipients 来源于辅料中的亚硝胺杂质对行业的挑战 • Dr. Fan Wu, Technical Director of Global Measurement Science, Ashland LLC
	11:10 – 11:40 a.m.	Title (TBD) • Dr. Jinqi Zheng 郑金琪, Director of Chemical Medicine, Zhejiang Institute for Food and Drug Control and NMPA Key Laboratory for Core Technology of Generic Drug Evaluation
11:40 - 1:00 p.m.	Break	
1:00 p.m. - 5:30 p.m.	Afternoon Session Moderator: Mr. Jie Liu, USP	
	1:00 – 1:30 p.m. (2:00-2:30 pm Japan, May 27th)	Current Status on Control of Nitrosamines in Marketed Products in Japan 日本上市药品中亚硝胺杂质控制现状 • Dr. Junichi Fukuchi, Principal Technical Officer, Office of Review Management, JP secretariat, PMDA

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	1:30 – 2:00 p.m.	Study on Chloropropanol Impurities in Pharmaceutical Excipients 药用辅料中氯丙醇杂质控制研究 • Dr. Ying Chen 陈英, Guangdong Institute for Drug Control and NMPA Key Laboratory for Quality Control and Evaluation of Pharmaceutical Excipients, Director of Pharmaceutical Excipients Department
	2:00 – 2:30 p.m. (11:30 a.m. - 12:00 p.m. India, May 27th)	Nitrosamine impurities – Current Regulatory Status 亚硝胺杂质 — 当前监管状态 • Dr. BM Rao, VP & Head - CQC, ASAT & EM QA, Dr. Reddy's Laboratories Limited
	2:30 – 3:00 p.m. (9:30 a.m.-10:00 a.m. Israel, May 27th)	Setting Limits for Complex Nitrosamines 复杂亚硝胺杂质限量的设定 • Dr. Raphael Nudelman, Senior Director Impurity Expert, R&D Operations, Teva Pharmaceutical Industries Ltd.
	3:00 – 3:30 p.m. (12:30 p.m.-1:00 p.m. India, May 27th)	Current Landscape in the US 美国亚硝胺杂质现况 • Dr. Aloka Srinivasan, Principal and Managing Partner, Raaha LLC
	3:30 – 4:00 p.m. (9:30 a.m. - 10:00 a.m. CEST, May 27th)	The EDQM Response to Nitrosamines 欧洲药典应对亚硝胺杂质 • Mr. Cristian Sampaolesi, Head of New Dossiers Section, Certification of Substances Department (DCEP), EDQM
	4:00 – 4:30 p.m. (10:00 a.m.- 10:30 a.m. Germany, May 27th)	Analytical Challenges 亚硝胺杂质分析方法的挑战 • Dr. Amanda Guiraldelli, Scientific Affairs Manager, USP
	4:30 – 5:00 p.m. (9:30 a.m. - 10:00 a.m. UTC+1, May 27th)	How Concerning is Your Nitrosamine? Using SAR to Evaluate Hazard and Potency 您是否为产品中的亚硝胺杂质焦虑？ 使用 SAR 评估危害及活性 • Dr. David Ponting, Principal Scientist, Lhasa Limited
	5:00 – 5:30 p.m. (10:00 a.m. - 10:30 a.m. UTC+1, May 27th)	N-Nitrosamines Light at the end of the Tunnel? or the end of the Road? N-亚硝胺杂质，隧道尽头的光明，还是路的尽头？ • Dr. Andrew Teasdale, Chair of AstraZeneca's Impurity Advisory Group, AstraZeneca