



## A Two-Day Educational Experience and Pharma Expo with in-depth Workshops & Education Sessions from Industry's Top-Excipient Experts

### Workshop Day

Tuesday, November 19<sup>th</sup>

VIP Hall, 2<sup>nd</sup> floor, North Star Continental Grand Hotel

- Workshop (9:00AM – 5:30PM)
- Lunch (12:30PM – 2:00PM)

### DAY 1

Wednesday, November 20<sup>th</sup>

- Welcome Speech (8:45AM)
- Pharma Expo (8:00 AM – 6:00 PM)
- Key-Note Speakers (9:00 AM - 12:00 PM)
- Lunch (12:00PM – 1:30PM)
- Educational Sessions (1:30 PM – 5:00 PM)
- ExcipientFest Lucky Draw (5:00 PM)

### DAY 2

Thursday, November 21<sup>st</sup>

- Pharma Expo (8:00 AM – 6:00 PM)
- Key-Note Speakers (8:45 AM - 12:00 PM)
- Lunch (12:20 – 2:00PM)
- Educational Sessions (2:00 PM – 4:15 PM)
- Closing Ceremony (4:15 PM)

## Educational Sessions (\*Invited)

DAY 1 Wednesday, November 20 <sup>th</sup>	
From 7:30 AM	Registration 注册
Conference Halls A and B	
8:45 – 9:00 AM	<p>Welcome Speech 开幕式致辞 Mr. Xue Bin (Chairman) – CCIPIE 薛斌 中国医药国际交流中心 副主任</p>
9:00 – 9:40 AM	<p>China Excipients' Regulation Update 中国辅料法规进展和后续执行要求 Department of Drugs &amp; Cosmetics Registration, CFDA 中国食品药品监督管理局 药品化妆品注册管理司</p>
9:40 – 10:20 AM	<p>Thoughts on Excipient DMF System in China 药用辅料备案管理制度 (DMF) 的探索与思考 Mr. Sun Humin, NIFDC 孙会敏 中国食品药品检定研究院 包装材料与药用辅料检定所 所长</p>
10:20 – 10:40 AM	Tea & Networking 茶歇与交流
10:40 – 11:20 AM	<p>Generic Drug Quality Consistency Evaluation 仿制药一致性评价概略 NIFDC 中国食品药品检定研究院 化学药品检定所</p>
11:20 – 12:00 PM	<p>China Pharmacopoeia Excipients Monograph Update 中国药典辅料标准增修订进展 Ms. Han Peng Chinese Pharmacopoeia Commission 韩鹏 国家药典委员会 业务综合处 副处长</p>
12:00 – 1:30 PM	Lunch & Networking 午餐与交流
Conference Hall A	
1:30 – 2:15 PM	<p>Risk assessment for Excipients 药用辅料风险评估 Mr. Frithjof Holtz – IPEC Europe IPEC 欧洲</p>
2:15 – 3:00 PM	<p>Case study of Generic formulation development and consistency evaluation 仿制药的处方研究和一致性评价的案例分折 Mr. Henry Han – Evonik Shanghai 韩海峰 赢创特种化学 (上海) 有限公司</p>
3:00 – 3:30 PM	Tea & Networking 茶歇与交流
3:30 – 4:15 PM	<p>Atypical Actives: Where are we going? 非典型性辅料: 路往何方? Ms. Janeen Skutnik – IPEC Federation IPEC 联盟</p>
4:15 – 5:00 PM	<p>Discussion on API and excipients sampling rule 抽样检验和原辅料抽样原则的探讨 Ms. Ding Wen Xing – China National Institute of Standardization 丁文兴 中国标准化研究院</p>
5:00 – 6:00PM	展区交流及抽奖 ExcipientFest Lucky Draw & Networking

DAY 2 Thursday, November 21 <sup>st</sup>	
From 7:30 AM	Registration
Conference Halls A and B	
8:45 – 9:25 AM	<p>Pharmaceutical Excipients' Classification and Quality Control 药用辅料的分级和质量控制 Mr. Tu Jiasheng – China Pharmaceutical University 涂家生 中国药科大学 教授</p>
9:25 – 10:05 AM	<p>Update on "Falsified Medicines Directive" 2011/62/EU in the European Union Impact on API and Excipients 欧洲假药指令(FMD)进展 Ms. Patricia Rafidison - IPEC Europe IPEC 欧洲</p>
10:05 – 10:20 AM	Tea & Networking
10:20 – 11:00 PM	<p>Current Topics for Pharmaceutical Excipients in IPEC Japan 日本药用辅料法规进展 Mr. Keiji Kijima – IPEC Japan IPEC 日本</p>
11:00 – 11:40 PM	<p>Excipient Regulation in India 印度辅料管理规章 Mr. Dave Schoneker – IPEC Federation IPEC 联盟</p>
11:40 – 12:20 PM	<p>Quality standards and technical requirements of Lecithin 卵磷脂的质量标准和技术要求 Speaker: Mr. Yang Rui – NIFDC 杨锐 中国食品药品检定研究院 包装材料与药用辅料检定所</p>
12:20 – 2:00 PM	Lunch & Networking
Conference Hall A	
2:00 – 2:45 PM	<p>Excipient Master File 药用辅料主控文件 Mr. Daniel Liu – IPEC China 刘晓海 – IPEC 中国</p>
2:45 – 3:30 PM	<p>Thoughts on future development of China pharmaceutical excipients manufacturer 中国药用辅料企业未来发展的思考 Mr. Yin Zheng long Anhui Sunhere Pharmaceutical Excipients Co.,Ltd. 尹正龙 安徽山河药用辅料股份有限公司 董事长</p>
3:30 – 4:15 PM	<p>Embracing Excipient GMPs from a Global Perspective 从全球视角审视药用辅料的 生产质量管理规范 (GMP) Ms. Janeen Skutnik – NSF International</p>
4:15 – 5:00PM	抽奖及闭幕式 ExcipientFest Lucky Draw & Closing Ceremony



**Full-Day Workshops** Speaker Biographies and Detailed Workshop Outlines Available at [www.excipientfest.asia](http://www.excipientfest.asia)

会前研讨班 Workshop Day – November 19<sup>th</sup> – Tuesday

IPEC Regulatory Considerations 国际药用辅料指南培训

**Presented by IPEC China:** The industry association that develops, implements, and promotes global use of appropriate quality, safety, and functionality standards for pharmaceutical excipients and excipient delivery systems.

五洲大酒店二层贵宾厅（紫罗兰厅）

VIP Hall, 2<sup>nd</sup> floor, North Star Continental Grand Hotel

7:00—8:30	Registration 注册
9:00—10:30	IPEC Certificate of Analysis Guide IPEC 药用辅料检验报告书(COA)指南 <b>Workshop Leader:</b> Mr. Colin Li – IPEC China 李崇林 IPEC 中国
10:30—11:00	Tea Break 茶歇
11:00—12:30	The IPEC Significant Change Guide IPEC 辅料重大变更指南 <b>Workshop Leader:</b> Mr. Dale Carter – IPEC Americas, Mr. Martin Tao – IPEC China Mr. Dale Carter – IPEC 美国 陶征宇 – IPEC 中国
12:30—14:00	Lunch 午餐
14:00—15:30	IExcipient Information Packages(EIPs) IPEC 辅料标准信息文件指南 <b>Workshop Leader:</b> Ms. Priscilla Zawislak – IPEC Americas, Ms. Meredith Ge – IPEC China Ms. Priscilla Zawislak – IPEC 美国 戈萌 – IPEC 中国
15:30—16:00	Tea Break 茶歇
16:00—17:30	Hot topics discussion: Excipient Import Inspection; Excipient Registration; Injectable Excipients Related Requirement 热点问题讨论: 进口辅料口岸药检; 辅料注册; 注射用辅料相关要求 <b>Workshop Leader:</b> Ms. Julia Zhu, Mr. Daniel Liu, Mr. Martin Tao, IPEC China 朱蕾、刘晓海、陶征宇—IPEC 中国

**REGISTER ONLINE AT**  
<http://www.excipientfest.asia>