

**良好药物包装规范：可提取物和浸出物**  
**Good Pharmaceutical Packaging: Extractables and Leachables**  
 2018年6月11-12日 上海

**日程 Agenda:**

时间 Time		主题 Topic	
第一天 Day 1  Jun. 11	8:30-9:00	签到	Registration
	9:00-12:00	可提取物与浸出物的定义和概念	Definitions and concepts for Extractables & Leachables (E&L)
		可提取物与浸出物研究的重要性和时间选择	Importance and timing of E&L studies
		整个药包材供应链的质量控制	Quality control throughout the supply chain of packaging materials
	12:00-13:00	午餐	Lunch
	13:00-16:30	可提取物与浸出物评估：总体考量	Extractables and Leachables Evaluation: General Considerations
		物料选择和早期评估	Material Selection and Early Assessment
		USP 通则 <1663>— 与药物包装和供应系统有关的药品可提取物评价	USP Chapter <1663> Assessment of Drug Product Extractables Associated with Pharmaceutical Packaging and Delivery Systems
16:30-17:00		问答	Q&A
第二天 Day 2  Jun. 12	9:00-12:00	USP 通则<1663>— 与药物包装和供应系统有关的药品可提取物评价（续）	USP Chapter <1663> Assessment of Drug Product Extractables Associated with Pharmaceutical Packaging and Delivery Systems (continued)
		可提取物的评估	Evaluation of Extractables
	12:00-13:00	午餐	Lunch
	13:00-16:30	USP 通则<1664>—与药物包装和供应系统有关的药品浸出物评价	USP Chapter <1664> Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging and Delivery Systems
		美国药典包装材料通则介绍（现行/新增/修订计划）	USP-NF Packaging General Chapters
16:30-17:00	问答	Q&A	

*This agenda is subject to change. 此表仅供参考，具体日程以最后版本为准*