良好药物包装规范：可提取物和浸出物
Good Pharmaceutical Packaging: Extractables and Leachables
2019 年 9 月 5-6 日　上海

日程 Agenda:

时间 Time		主题 Topic	
第一天 Day 1 Sep. 5th	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 Sep. 6th	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
		FDA 关于可提取物和浸出物常见问题指南	FDA's Guidance on Frequently Encountered Issues With E&L Filing
	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

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