

## 附件 1: 课程日程安排表 Agenda

**美国药典非无菌与无菌药物的微生物质量控制与检测精要**  
**Essentials of Control and Testing of Microbial Quality of Nonsterile and Sterile Products**  
 2019 年 11 月 18-19 日 广州

## 日程表 Agenda:

时间 Time		主题 Topic	
第一天 Day 1 Nov. 18	8:30-9:00	签到	Registration
	9:00-12:00	<1117> 良好微生物实验室规范	<1117> Microbiological Best Laboratory Practices
		微生物实验数据的可变性	Variability of Microbiological Data
		实验室调查基本要素	Basics of Laboratory Investigations
	12:00-13:00	午餐	Lunch
	13:00-17:30	<61> 非无菌产品的微生物检测: 细菌计数测试	<61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests
		<62> 非无菌产品的微生物检测: 控制微生物测试	<62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms
		<1111> 非无菌药物制剂和药用原料的接受标准及微生物污染控制	<1111> Acceptance Criteria for Nonsterile Pharmaceutical Preparations and Substances for Pharmaceutical Use, and Control of Micro Contamination
<60>非无菌产品微生物检测-洋葱伯克霍尔德菌群检测 (即将生效)		<60> Microbiological Examination of Nonsterile Products Tests for Burkholderia Cepacia Complex (to be official on 1-Dec-2019)	
<1227>微生物回收率验证 (最新修订)		<1227> Validation of Microbial Recovery from Pharmacopeial Articles (revision)	
17:30-18:00	问答	Q&A	
第二天 Day 2 Nov. 19	9:00-12:00	<71>无菌测试	<71> Sterility Tests
		<1071>短生命周期产品的快速无菌检测-基于风险的方法 (即将生效)	<1071> Rapid Sterility Testing of Short Life Products A Risk Based Approach (to be official on 1-Dec-2019)
	12:00-13:00	午餐	Lunch
	13:00-17:30	<85>细菌内毒素试验	<85> Bacterial Endotoxins Test
		<1229>药典物质灭菌	<1229> Sterilization of Compendial Articles
17:30-18:00	<1116>无菌工艺环境中的微生物控制和监测	<1116> Microbiological Control and Monitoring of Aseptic Processing Environments	
	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