

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 8 月 19-20 日 上海

日程表 Agenda:

时间 Time		主题 Topic	
第一天 Day 1 Aug. 19	8:30-9:00	签到	Registration
	9:00-12:00	微生物基础概述	Overview of Micro Basic
		<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
	13:00-17:00	<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
		<1112> 非无菌药品中水分活性确定的应用	<1112> Application of Water Activity Determination to Nonsterile Pharmaceutical Products
17:00-17:30	问答	Q&A	
第二天 Day 2 Aug. 20	9:00-12:00	<1115> 非无菌药物原料和药品的微生物控制	<1115> Bioburden Control in Nonsterile Drug Substances and Products
		<71> 无菌测试	<71> Sterility Tests
		<1227> 微生物回收率验证 (最新修订)	<1227> Validation of Microbial Recovery from Pharmacopeial Articles (revision)
	12:00-13:00	午餐	Lunch
	13:00-17:00	<85> 细菌内毒素试验	<85> Bacterial Endotoxins Test
		<1229> 药典物质灭菌	<1229> Sterilization of Compendial Articles
		<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
		<60> 非无菌产品微生物检测-洋葱伯克霍尔德菌复合体检测、<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)	<60> Microbiological Examination of Nonsterile Products Tests for Burkholderia Cepacia Complex; <1071> Rapid Sterility Testing of Short Life Products A Risk Based Approach (to be official on 1-Dec-2019)
17:00-17:30	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