

## 美国药典微生物检测精要 Essentials of USP Microbiological Testing 2017年11月13-14日 上海

### 日程表 Agenda:

| 时间 Time                 |             | 主题 Topic  |   |
|-------------------------|-------------|---|---|
| 第一天<br>Day 1<br>Nov. 13 | 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、<1115>非无菌药物原料和药品的微生物控制 | <1111> Acceptance Criteria for Nonsterile Pharmaceutical Preparations and Substances for Pharmaceutical Use, and Control of Micro Contamination, <1115> Bioburden Control of Non-Sterile Drug Substances and Products |
|                         |             | <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   |   |
| 第一天<br>Day 2<br>Nov. 14 | 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  | <1227> Validation of Microbial Recovery from Pharmacopeial Articles   |
|                         | 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  |
| 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