

## 美国药典在线点播课程 *USP On-Demand Webinar*

### 容器密封系统完整性：方法和应用 Container Closure Integrity Methods and Application

课程时长 **Course Duration:** 5小时 5 hours

#### 课程介绍 **Course Description:**

课程将讨论美国药典通则<1207>包装完整性评估系列的通则内容。课程重点介绍在无菌环境下各种容器密封完整性（CCI）的检测技术，并提供在整个药品生命周期中泄漏检测技术的选择和应用的系统方法。

通过学习，您将能够：

- 了解 USP 通则<1207>关于 CCI 的建议
- 通过基于风险的方法来阐述 CCI 对于各种容器和药物产品类型的要求
- 解释各种 CCI 检测技术的原理及其实际应用
- 解释 CCI 检测方法的开发、验证及最佳实践

*(该课程的现场版本录制于 2021 年 1 月 11-12 日)*

This course discusses the USP Package Integrity Evaluation <1207> series of general chapters. This course will focus on the practical aspects of various Container Closure Integrity (CCI) test technologies in the overall context of sterility assurance and provides a systematic approach to the selection and application of these leak test technologies throughout the drug product lifecycle.

*(The live version of this recording took place on January 11-12, 2021.)*

Upon completion of this course, you will be able to:

- Describe <1207> recommendations on CCI.
- Define CCI requirements for various container and drug product types using a risk-based approach.
- Explain principles of various CCI testing technologies and their practical applications.
- Define CCI test method development and validation approaches and best practices.

#### 参课对象 **Who Should Attend:**

注射用药物包装工程师和配方科学人员、实验室科学人员和管理者、注射用药物生产人员、无菌QA人员、法规事务人员、药物包装组件生产人员等。

Parenteral drug packaging engineers and formulation scientists, Laboratory scientific staff and managers, Parenteral manufacturing staff, Sterility QA staff, Regulatory affair scientists, Pharmaceutical packaging component manufacturing staff.

#### 授课语言 **Language:**

英语（含中文字幕） English (with Chinese subtitle)

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#### 讲师介绍 **Instructor:**

**Leslie Furr**, 美国药典委员会科学部门通则组资深科学家

**Leslie Furr, Senior Scientist II, Science-General Chapters, USP**

Leslie Furr 是美国药典委员会科学部门通则组资深科学家。自 2018 年以来, Leslie 担任 USP 包装和流通、制剂和微生物专家委员会的科学事务联络员。在此之前, 她是 USP 化学药专家委员会委员, 她的专长是抗生素检测。自 2012 年以来, 她持有美国微生物学会证书, 是制药和医疗器械领域的专业微生物学家。在进入 USP 之前, 她是制药行业的资深微生物学家。她在非无菌产品的方法开发、研发和生产支持方面拥有 14 年经验。她在北卡罗莱纳大学 (夏洛特校区) 获得微生物学学士学位, 在佛罗里达大学获得 EMS 和药学硕士学位。

Leslie Furr is a Senior Scientist II to the Compendial Science-General Chapters group at the USP. She has been with USP since 2018 where she is a liaison to the Packaging and Distribution, Dosage Forms, and Microbiology Expert Committees. Before becoming a liaison at USP she was an Expert Committee volunteer for the Chemical Medicines group with expertise in antibiotic testing. She holds a certification from the American Society for Microbiology as a Specialist Microbiologist in Pharmaceutical and Medical Device since 2012. Prior to working at USP, she was a Senior Microbiologist in the pharmaceutical industry where she spent 14 years in method development, R&D, and manufacturing support for non-sterile products. She obtained her B.S. in Microbiology from the University of North Carolina at Charlotte and her M.S. in Pharmaceutical Sciences at the University of Florida.

#### 课程有效期 **Access Duration:**

课程在线观看有效期: 自在线报名并缴费成功日起, 14 天内有效, 逾期课程访问通道将自动关闭。

(报名成功后您会收到课程登录信息通知邮件)

This course will be only available to you for 14 days from the day of successful registration or until you mark it 'Complete' in your transcript- whichever occurs first.

#### 培训费用 **Fee:**

1200 元人民币/人 RMB 1200/attendee

#### 报名方式 **Register Procedures:**

1. 点击[这里](#) ([课程报名](#)) 进行在线报名。

USP-China 收款账户: USP-China account

收款人 Beneficiary: 美药典标准研发技术服务 (上海) 有限公司

账号 Account No.: 6841 12464 120

银行 Bank: 美国银行有限公司上海分行

2. 发票领取: 报名成功后快递/邮寄方式提供 Invoice is available by express after successful registration.