

## 美国药典在线点播课程 *USP On-Demand Webinar*

### 使用重组试剂的细菌内毒素检查法 Bacterial Endotoxins Test Using Recombinant Reagents

课程时长 **Course Duration:** 1小时 1 hour

#### 课程介绍 **Course Description:**

课程深入探讨 USP 通则<86> “使用重组试剂的细菌内毒素检查法” (BET)，帮助学员将全面了解内毒素测试在确保产品安全和符合监管要求方面的重要意义。

课程将介绍细菌内毒素及其来源、以及对人类健康的影响，强调准确检测药品 (特别是经胃肠外给药的药品) 中内毒素的重要性。学员将了解使用重组试剂 (如重组因子 C (rFC) 和重组级联试剂 (rCR)) 的优势，为传统检查法提供了一种非动物来源的替代方法。学员将探索使用重组试剂进行 BET 所涉及的方法，包括制备内毒素标准溶液、使用荧光和显色技术以及结果阐述。课程还将讨论当前的监管要求和将重组试剂用于内毒素检查法的最佳实践，为应对合规挑战提供帮助。

通过学习，您将能够：

- 定义细菌内毒素并解释其在药物测试中的重要性
- 识别并描述 BET 中使用的重组试剂和检测技术
- 识别并解释当前使用重组试剂进行内毒素测试的监管要求
- 对有 BET 各论要求的产品实施检测方法

This course provides an in-depth examination of the Bacterial Endotoxins Test (BET) using recombinant reagents. Participants will gain a comprehensive understanding of the significance of endotoxin testing in ensuring product safety and compliance with regulatory standards.

The course begins with an overview of bacterial endotoxins, their sources, and their implications for human health. It highlights the importance of accurate endotoxin detection in pharmaceutical products, particularly those administered parenterally. Participants will learn about the advantages of using recombinant reagents, such as recombinant Factor C (rFC) and recombinant cascade reagents (rCR), which offer a non-animal-derived alternative to traditional testing methods.

Participants will explore the methodologies involved in performing the BET using recombinant reagents. This includes preparation of standard endotoxin solutions, execution of both fluorometric and chromogenic techniques, and interpretation of results.

The course will also address current regulatory requirements and best practices for incorporating recombinant reagents for endotoxin testing, equipping participants with the knowledge to navigate compliance challenges effectively.

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

- Define bacterial endotoxins and explain their significance in pharmaceutical testing.
- Identify and describe the recombinant reagents and testing techniques used in BET.
- Identify and explain current regulatory requirements for endotoxin testing using recombinant reagents.
- Implement testing methods for products that have a monograph requirement for BET.

#### 参训对象 **Who Should Attend:**

制药行业的微生物专业人士、质量控制 (QC) 人员、质量保证 (QA) 人员和法规事务专员

Pharmaceutical microbiologists, quality control (QC) scientists, quality assurance (QA) professionals, and regulatory affairs specialists

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### 使用重组试剂的细菌内毒素检查法 Bacterial Endotoxins Test Using Recombinant Reagents

**授课语言 Language:** 英语（含中文字幕） English (with Chinese subtitle)

#### 讲师介绍 Instructor:

**Leslie Furr**, 美国药典委员会微生物通则资深科学家

**Leslie Furr, Principal Scientist, Microbiology, Science-General Chapters, USP**

Leslie Furr 是美国药典委员会微生物通则资深科学家。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。她持有美国微生物学会证书，是制药和医疗器械领域的微生物专家。在加入 USP 之前，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。Leslie 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 Principal Scientist of Microbiology for Science-General Chapters at 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:** 200 元人民币/人 RMB 200/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：电子发票通过电子邮件发送 e-Invoice is available by email after successful registration.