

美国药典在线点播课程 *USP On-Demand Webinar* DNA 残留测定 Residual DNA Testing

课程时长 Course Duration:

45分钟 45 minutes

课程介绍与目的 Course Description and Objectives:

DNA 残留测定被用于证明从生产细胞基质产生的宿主 DNA 在治疗用生物制剂中已完全被清除。课程概述了美国药典新提议的通则<509> DNA 残留测定，其中包含对大肠杆菌或仓鼠卵巢基因细胞 DNA 进行检测的药典方法。为了支持这些方法，已经制定了 USP 标准物质 (RS) 来评估这些分析方法的系统适用性。

课程还将讨论 USP 通则 <1130>核酸检测技术方法 (DNA 残留测定) 中分析其他残留 DNA 方法的最佳实践。在通则<1130>和本课程中描述的分析方法包括杂交法、使用与 ssDNA 有亲和力的 DNA 结合蛋白进行测试、定量 PCR (q-PCR)。

通过学习，您将了解：

- 如何使用为生物样品中 DNA 残留的测定提供分析方法的 USP 新通则
- 考虑每种检测方法的优缺点，指导选择检测方法
- 如何应用相关的标准物质来评估分析方法的系统性能

Residual DNA testing is required to demonstrate clearance of DNA from the cell substrate used to manufacture biologics for therapeutic use. This webinar provides an overview of the newly proposed USP Chapter <509> Residual DNA Testing containing validated methods for measurement of either E. coli or Chinese Hamster Ovary (CHO) genomic DNA in such products. To support these methods, a USP Reference Standard (RS) has been developed to assess the system suitability for these analytical procedures.

This course will also discuss best practices for other residual DNA methods that are found in USP General Chapter <1130> Nucleic-Acid Based Techniques—Approaches for Detecting Trace Nucleic Acids (Residual DNA Testing). The analytical procedures described in General Chapter <1130> and in this course include Hybridization, Tests using DNA binding proteins that have affinity for ssDNA, Quantitative PCR (q-PCR).

By taking this course, you will learn

- How to access USP's new general chapter that provides analytical procedures for measurement of residual DNA in biological samples
- Guidance on assay selection taking into consideration the advantages and disadvantages of each assay
- How to apply the associated Reference Standard to assess system performance for the analytical procedures

参课对象 Who Should Attend:

QA/QC 专员和审核员；从事研发、制造和生产的实验室人员；制造业研究员和管理者；CRO/CMO 企业人员；科研人员；批记录审核员；验证专员等。

Quality assurance and quality control specialists and auditors; Lab personnel in research and development, manufacturing, and production; Manufacturing scientists and managers; Contract research/manufacturing organizations; Scientists and researchers; Batch record reviewers; Validation specialists.

报名请登录 USP 会议与培训中文平台，[点击这里](#) ([课程报名](#)) 进行在线报名

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DNA 残留测定 Residual DNA Testing

讲师介绍 Instructor:

Maura C. Kibbey 博士, 美国药典委员会科学部门全球生物高级研究员

Maura C. Kibbey, Ph.D., Sr Scientific Fellow, Science - Global Biologics, U.S. Pharmacopeia

Maura Kibbey 博士是 USP 全球生物部门教育和培训高级科学研究员。Kibbey 博士与其他科学专家和讲师一起, 致力于为 USP 生物制品的利益相关者带来更多的专业课程。在担任教育和培训高级科学研究员之前, Kibbey 博士负责管理一个科学事务联络员小组, 与 USP 五个专家委员会和多个生物制剂、多肽和抗生素专家小组共同合作, 制定支持生物制药质量评估和开发的标准。在加入 USP 之前, Kibbey 博士就职于华盛顿特区的生物技术和诊断公司、以及美国国立卫生研究院。她的科学专长包括开发和验证许多不同的测试类型, 用于测量单个分子、它们的活性或相互作用。她发表了 40 多篇同行评议的文章, 并被邀请为许多科学会议的演讲者或研讨会组织者。

Dr. Maura Kibbey is Senior Scientific Fellow for Education and Training in USP's Global Biologics Department. Dr. Kibbey collaborates with scientific experts and trainers to bring more educational offerings to USP's biologics stakeholders. Previously, Maura directed a team of liaisons working with the five USP Expert Committees and multiple Expert Panels for biologics, peptides, and antibiotics to develop standards that support biopharmaceutical quality assessment and development. Before joining USP, Dr. Kibbey worked for several biotechnology and diagnostic companies in the Washington DC area as well as at the National Institutes of Health. Her scientific expertise includes development and validation of many different assay types for measurement of individual molecules, their activities, or binding interactions. She has published over 40 peer-reviewed articles and has been an invited speaker or workshop organizer for numerous scientific conferences.

授课语言 Language:

英语 (含英文字幕) English (with English subtitles)

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用户名、密码邮件)

Access to this course expires 14 days from the date of registration or until you mark it 'Complete' in your transcript—whichever occurs first.

培训费用 Fee: 600 元人民币/人 RMB 600/attendee

报名方式 Register Procedures:

1. 请点击这里 ([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: 快递/邮寄方式提供 Invoice is available after registration.