

## 美国药典在线点播课程 USP On-Demand Webinar

### 生物制品中宿主细胞蛋白残余测定

### Residual Host Cell Protein Measurement in Biopharmaceuticals

课程时长 **Course Duration:** 80分钟 80 minutes

#### 课程介绍与目的 **Course Description and Objectives:**

宿主细胞蛋白 (HCP) 的残留测定在治疗用生物制剂的开发、表征和放行过程中至关重要。美国药典 (USP) *通则*<1132>生物制品中宿主细胞蛋白残余测定描述了确定生物制品中 HCP 所带来的杂质和风险的复杂性与挑战。课程阐述了美国药典对生物制药中 HCP 评估的建议，分享了最常见/广泛使用的 HCP 分析方法的开发和验证的最佳实践，并介绍了正交法作为了解生产池中 HCP 种群的新工具，用于帮助鉴定关键试剂。

在课程中您将学习：

- 提供测定生物样品中 HCP 残留量的分析方法的 USP 通则；
- HCP 杂质给生物制造带来的挑战和风险；
- 基于广泛的抗原人群和在纯化过程中不断变化的样本基质，如何遵循监管的期望和指导来开发和验证 HCP 检测方法。

Residual Host Cell Protein (HCP) measurement is critical during process development, characterization, and release of biologics for therapeutic use. This webinar provides an overview of USP's recommendations for the evaluation of HCP in biopharmaceuticals. USP General Chapter <1132> Residual Host Cell Protein Measurement in Biopharmaceuticals describes the complexity and challenges in determining such impurities and risks presented by the presence of HCP in biologicals. This webinar also provides best practices for development and validation of the most commonly and broadly used analytical procedures for determination of HCP, and an introduction to orthogonal methods as new tools for understanding the HCP population in a manufacturing pool and to help qualify critical reagents.

By taking this course, you will learn:

- How to access USP's general chapter that provides analytical procedures for measurement of residual HCP in biological samples
- The challenges and risks presented by HCP impurities for biologic manufacturing
- How to develop and validate HCP assay methods following the regulatory expectations and guidance, given the wide antigen population that they measure and the varying sample matrices over the purification process

#### 参课对象 **Who Should Attend:**

生物制品企业技术人员和管理者 Manufacturing scientists and managers

#### 授课语言 **Language:**

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

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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### 生物制品中宿主细胞蛋白残余测定

#### Residual Host Cell Protein Measurement in Biopharmaceuticals

##### 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.

##### 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。

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. 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.