

## 美国药典在线点播课程 *USP On-Demand Webinar*

### 生物制造原料和细胞基质的鉴定

## Qualification of Raw Materials and Cell Substrates for Biomanufacturing

课程时长 **Course Duration:** 35分钟 35 minutes



免费视频课!

#### 课程介绍 **Course Description:**

起始物料的质量是成功的药品生产战略的关键。在生物制造方面，由于使用了各种原料、细胞系和天然衍生材料，增加了引入不必要的杂质和外来因素的风险，因此挑战进一步被放大。课程介绍了美国药典相关标准及更新信息，包括来料确认、病毒清除/ 低温贮藏/细胞库证明、治疗性蛋白细胞基质的杂质控制的最佳实践。

The quality of starting materials is critical for successful pharmaceutical manufacturing strategies. For biomanufacturing the challenges are further amplified due to the use of a wide variety of raw materials, cell lines, and naturally-derived materials with an increased risk for the introduction of unwanted impurities and adventitious agents. This presentation will provide an overview and updates on USP documentary standards containing best practices for qualifying incoming materials, demonstrating viral clearance, cryopreservation, cell banking, and controlling impurities derived from cell substrates for therapeutic proteins.

#### 参课对象 **Who Should Attend:**

对生物技术感兴趣的科研人员、管理人员和监管机构工作者  
Global scientists, Managers, and Regulators interested in biotech topics

#### 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培训课程。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.

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#### 授课语言 Language:

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

#### 报名方式 Register Procedures:

本课程免费！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。

#### 课程有效期 Access Duration:

课程在线观看有效期：自在线报名成功日起，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.