

美国药典在线点播课程 *USP On-Demand Webinar*

美国药典通则<129>重组治疗性单克隆抗体的分析方法 *USP-NF General Chapter <129> Analytical Procedures for Recombinant Therapeutic Monoclonal Antibodies*

课程时长 **Course Duration:** 50分钟 50 minutes



免费视频课!

课程介绍 **Course Description:**

课程介绍了用于治疗单克隆抗体的质量属性评估方法。在美国药典通则<129>中描述的经过验证的方法包括通过尺寸排阻色谱法、毛细管电泳法和寡糖分析法来测定纯度。USP 标准品可用于支持这些方法。

通过学习，您将能确定用于评价治疗性单克隆抗体质量属性的方法；学会描述通则<129>中经验证的方法，包括纯度测定的方法；并能解释如何使用 USP 标准品来评估通则<129>中分析方法的系统适用性。

This 50-minute webinar will cover the procedures used to evaluate the quality attributes of monoclonal antibodies for therapeutic use. The validated methods that are described in USP-NF General Chapter <129> include purity determination by size-exclusion chromatography, capillary electrophoresis and analysis of oligosaccharides. A USP reference standard has been developed to support these methods.

Upon completion of this course, you will be able to identify procedures used for evaluation of quality attributes of therapeutic monoclonal antibodies, describe the validated methods in Chapter <129>, including purity determination, explain how the USP Reference Standard is used to assess the system suitability of the chapter's analytical procedures.

参课对象 **Who Should Attend:**

分析科学工作者、QA/QC 人员、R&D 研究员及其管理者、生产研究员及其管理者、法规事务专员、CRO 和 CMO 企业工作者。

Analytical scientists, QA/QC analysts, R&D scientists and managers, Manufacturing scientists and managers, Regulatory affairs specialists, Contract research organizations, Contract manufacturing organizations.

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信息通知邮件）

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