

## 美国药典在线点播课程 USP On-Demand Webinar

# 生物治疗药物的特性表征 Characterization of Biotherapeutics

课程时长 **Course Duration:** 30分钟 30 minutes



免费视频课!

### 课程介绍 **Course Description:**

生物治疗产品的典型特征是采用多种正交方法来评价产品质量和纯度，包括评价聚合体、变体和降解产品。对于单克隆抗体和许多其他生物疗法而言，分析翻译后修饰（如糖基化）也很重要，因为这些修饰会影响最终产品的疗效、稳定性和安全性。课程将概述在表征过程中使用的方法和标准，并重点介绍单克隆抗体。您将学习鉴定单克隆抗体特性的多种方法，以及使用 USP 生物制品标准来支持测试。

Biotherapeutic products are typically characterized by multiple orthogonal methods to evaluate product quality and purity, including assessment of aggregates, variants, and degradation products. For monoclonal antibodies and many other biotherapeutics, analysis of post-translational modifications, such as glycosylation, are also important since these modifications can impact the efficacy, stability, and safety of the final product. This presentation will provide an overview of methods and standards used during characterization, with an emphasis on monoclonal antibodies. By taking this course, you will learn identifying multiple methods for characterization of monoclonal antibodies, and recognizing the USP Biologics standards that support this testing.

### 参课对象 **Who Should Attend:**

分析科学工作者、QA/QC 分析员、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 专员。

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:**

**Diane McCarthy 博士，美国药典委员会全球生物部门科学与标准高级经理**

**Diane McCarthy, Ph.D., Senior Manager, Science & Standards, Global Biologics, USP**

McCarthy 博士是 USP 美国药典委员会全球生物部门科学与标准高级经理。她与利益相关者们通力合作确定哪些领域需要标准，并定义和开发新的标准。在加入 USP 之前，McCarthy 博士担任 Caprion Biosciences 公司高级科学总监，从事用质谱来表征生物制品和宿主细胞蛋白方面的工作。此外，她还曾担任 Ezose Sciences 公司科学事务部总监，负责多糖的质谱法鉴别和定量工作，以及 Bio-Rad 公司生物标志物研究中心全球经理，负责指导转化和生物标记研究合同，以及与行业、协会、学术和政府团体之间的合作。

Dr. McCarthy is a senior manager of science and standards within USP's Global Biologics department. She works with stakeholders to identify areas where standards are needed and defined and develop new standards. Prior to joining USP, Dr. McCarthy was senior scientific director at Caprion Biosciences, where she focused on the use of mass spectrometry for characterization of biologics and host cell proteins. Her previous roles also included Director of Scientific Affairs at Ezose Sciences, where she focused on identification and quantification of glycans by mass spectrometry, and Global Manager of Biomarker Research Center at Bio-Rad Laboratories, where directed translational and biomarker research contracts and collaborations with industry, key consortia, academic and government groups.

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生物治疗药物的特性表征  
Characterization of Biotherapeutics

**授课语言 Language:**

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

**报名方式 Register Procedures:**

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**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.