

美国药典在线点播课程 *USP On-Demand Webinar*

生物制品中的杂质监测

Monitoring Impurities in Biologics

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

课程介绍 **Course Description:**

生物治疗产品及其生产过程的复杂性可能会产生多种杂质，必须对这些杂质进行监测和控制，以最大限度地减少安全问题，并确保产品质量。这些杂质可大致分为两类：1) 产品杂质，例如前体、聚合物和降解物；2) 工艺杂质，例如宿主细胞 DNA、宿主细胞蛋白和微粒物。

课程将概述杂质的监测方法，包括讨论杂质测试的现有美国药典标准和开发中的标准；介绍产品杂质和工艺杂质的区别，USP 生物制剂杂质的相关通则，以及开发中的 USP 生物标准品。

The complexity of biotherapeutic products and their manufacturing processes can yield a variety of impurities, which must be monitored and controlled to minimize safety concerns and ensure product quality. These impurities can be broadly grouped into two categories: 1) product-related impurities, such as precursors, aggregates and degradation products, and 2) process-related impurities, such as host cell DNA, host cell protein, and particulates. This presentation will provide an overview of approaches for monitoring impurities, including a discussion of existing USP standards and standards under development to support impurity testing.

By taking this course, you will learn

- Explain the difference between product- and process-specific impurities
- Describe USP Chapters to support impurities in biologics
- State new USP reference materials in development for biologics

参课对象 **Who Should Attend:**

生物制药/CRO/CMO 企业的生物分析员、QA/QC 人员、研发实验员/研发经理、生产技术人员/经理、法规事务人员等。

Analytical biologists, QA/QC analysts, R&D scientists, managers; Manufacturing scientists, 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总监

Diane McCarthy, Ph.D., Senior Director, 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总监。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 director 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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授课语言 Language:

英语（含中文字幕） English (with Chinese subtitles)

课程有效期 Access Deadline: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信息通知邮件）

This course will be only available to you for 14 days from the day of successful registration or until you mark it 'Complete' in your transcript– whichever occurs first.

培训费用 Fee: 200 元人民币/人 RMB 200/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 by express after successful registration.