

美国药典在线点播课程 *USP On-Demand Webinar*

N-糖分析：新的药典分析方法与相关标准品 N-linked Glycan Analysis: New Compendial Procedures and Associated Reference Standards

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



免费视频课!

课程介绍 **Course Description:**

在重组治疗性糖蛋白的表征研究及其产品放行测试中，天冬酰胺上的寡糖（也称 N-糖）分析十分重要。课程概括和介绍了糖基化分析标准的美国药典方法，并对释放后 N-糖的药典表征分析方法进行了深入阐述。USP 通则<212>“寡糖分析”包含七种验证过的分析方法和测试标准，可应用于不同种类的 N-糖，例如结构相对简单的不含或含有少量唾液酸的双天线糖型、更复杂的多唾液酸结构等。针对这些方法，USP 开发了四种标准品用于考察方法的系统适应性。此外，USP 通则<210>“单糖分析”为唾液酸的定量分析提供了经验证的分析方法和三个 USP 标准品。课程将详细讨论这些方法及标准品的应用。

在课程中您将学习如何访问提供释放后 N-糖表征分析方法的 USP 通则、运用 USP 方法对治疗性糖蛋白中 N-糖进行分析、以及应用相关标准品来评估分析方法的系统性能。

Analysis of the Asn-linked oligosaccharide (also known as N-linked glycan) composition of recombinant therapeutic glycoproteins has become necessary for product characterization and release specifications of these proteins. This webinar provides an overview of USP's approach on glycosylation analysis standards and an in-depth explanation of compendial procedures for profiling released N-linked glycans. General Chapter <212> Oligosaccharide Analysis consists of several validated analytical procedures and performance criteria to analyze various types of N-linked glycans, from relatively simple bi-antennary chains with no or low levels of sialylated structures to more complex multi-sialylated structures. To support these methods, four USP Reference Standards (RSs) have been developed to assess the system suitability for these analytical procedures. In addition, General Chapter <210> Monosaccharide Analysis provides validated analytical procedures for quantitation of sialic acids, and is accompanied by three USP Reference Standards. Details of these methods and the applications of RSs are discussed in this course.

Upon completion of this course, you will learn how to

- Access USP's general chapters that provide analytical procedures for profiling released N-linked glycans
- Use and apply the compendial procedures for analysis of N-linked glycans released from a therapeutic glycoprotein of interest
- Apply the associated reference standards to assess system performance for the analytical procedures

参课对象 **Who Should Attend:**

QA/QC 分析员、生化专业人员、糖生物专业人员、R&D 研究员和经理、生产研究员及其管理者、CRO 和 CMO 工作人员。

QA/QC analysts, Biochemists, Glycobiologists, R&D scientists and managers, Manufacturing scientists and managers, Contract research/manufacturing organizations

授课语言 **Language:**

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

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N-糖分析：新的药典分析方法与相关标准品

N-linked Glycan Analysis: New Compendial Procedures and Associated Reference Standards

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.

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.