美 国 药 典 在 线 点 播 课 程 USP On-Demand Webinar

支持单克隆抗体表征的美国药典标准：应用和通则<129>
USP Standards to Support the Characterization of mAbs: Applications and General Chapter 129

课程时长 Course Duration: 1小时5分钟 1hr 5 minutes

课程介绍 Course Description:

美国药典提供用于评估治疗用单克隆抗体(mAbs)质量属性的解决方案。美国药典通则<129>“重组治疗性单克隆抗体的分析方法”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。除这些方法外，课程还将介绍使用 SEC-UHPLC 的 mAbs 分析方法及其在通则<129>中的内容。mAbs 的开发过程中也会产生杂质，如宿主细胞蛋白和残留 DNA，课程将介绍检测工艺相关杂质的 USP 解决方案。本课程还将讨论使用多属性方法(MAM)对 mAbs 进行分析测试。最后，课程将通过 USP 标准物质的案例来阐述这些分析方法的应用。

课程主题包含：

- 评估通则<129>和其他章节中治疗用单克隆抗体质量属性的方法
- 用于检测 mAbs 产品和工艺相关杂质的 USP 解决方案
- 用于评估系统适用性或作为分析方法开发工具的 USP 标准物质

USP offers solutions to evaluate the quality attributes of monoclonal antibodies (mAbs) for therapeutic use. The validated methods that are described in USP–NF General Chapter <129> *Analytical Procedures for Recombinant Therapeutic Monoclonal Antibodies* include purity determination by size-exclusion chromatography, capillary electrophoresis, and analysis of glycans. In addition to these methods, this webinar will cover analytical procedures for mAbs using SEC-UHPLC and its inclusion in chapter <129>. The development of mAbs is also marked by impurities such as host-cell proteins and residual DNA and this webinar will present USP solutions to detect process-related impurities. The use of Multi-Attribute Method (MAM) for analytical testing of mAbs will also be discussed. Lastly, the applications of these analytical methods will be demonstrated through case studies highlighting USP Reference Standards. Topics include:

- Procedures used for evaluation of quality attributes of therapeutic monoclonal antibodies included in Chapter <129> and other chapters.
- USP solutions for the detection of product- and process-related impurities for mAbs.
- USP Reference Standards and materials used to assess system suitability, or as a tool for analytical method development.

参课对象 Who Should Attend:

QA/QC 分析人员、R&D 科学人员和管理者、生产科学人员和管理者、生物化学人员、CRO/CMO 以及法规人员。
QA/QC analysts, R&D scientists and managers, Manufacturing scientists and managers, Biochemists, Contract research/manufacuring organizations and Regulatory professionals

讲师介绍 Instructor:

Niomi Peckham, 美国药典全球生物制品管线开发总监
Niomi Peckham, Director of Pipeline Development, Science-Global Biologics, USP

Niomi Peckham 毕业于纽约州立大学石溪分校，拥有分子和细胞生物学硕士学位。她曾就职于辉瑞和 Alexon 多家国际知名药企，负责生物制品相关分析方法的开发、验证、转移和生命周期管理。Niomi 目前是美国药典全球生物制品管线开发总监，她与业界专家和利益相关方协作共同负责 USP 生物制品相关标准的开发，参与单抗药物、细胞和基因治疗等多个领域标准和分析方法的开发和建立。

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讲师介绍 Instructor*(cont.)*:

Ms. Peckham holds a Master of Science in Molecular and Cellular Biology from the State University of New York at Stony Brook. Ms. Peckham has worked for several biotechnology and diagnostic companies but has spent most of her career at Pfizer and Alexion Pharmaceuticals, focusing on development, validation, transfer, and lifecycle management of analytical methods for biopharmaceuticals. Ms. Peckham is now the Director of Pipeline Development in USP's Global Biologics Department. She works with scientific experts and stakeholders to develop standards for biologics and participates the development and establishment of standards and analytical methods of monoclonal antibodies, cell and gene therapy.

景丽博士, 美国药典全球生物制品资深科学家
Dr. Li Jing, Principal Scientist, Global Biologics, USP

景丽博士是USP全球生物制品部门的资深科学家。景博士领导一个联络员团队，与USP专家委员会和多个蛋白质、多肽和碳水化合物专家顾问组共同协作，制定支持生物药质量评估和开发的标准。近期，景博士与USP MAM专家顾问组合作，制定“通则<1060>基于质谱的治疗性蛋白多属性方法”。景博士拥有美国佐治亚大学分析化学博士学位，以及复旦大学化学学士学位。她曾就职于多家生物技术和制药公司，专注于蛋白疗法和候选疫苗的开发。

Dr. Li Jing is a Principal Scientist in USP's Global Biologics Department. Dr. Jing leads a team of liaisons working with the USP Expert Committees and multiple expert panels for proteins, peptides, and carbohydrates to develop standards that support biopharmaceutical quality assessment and development. Recently, Dr. Jing worked with the USP MAM Expert Panel and developed General Chapter <1060> Mass Spectrometry Based Multi-Attribute Method for Therapeutic Proteins. Dr. Jing holds a Ph.D. in Analytical Chemistry from the University of Georgia and a B.S. in Chemistry from Fudan University. Dr. Jing has worked for several biotechnology and pharmaceutical companies, focusing on the development of protein therapeutics and vaccine candidates.

授课语言 Language: 英语（含中文字幕） English (with Chinese subtitles)

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.

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：电子发票通过电子邮件发送 e-Invoice is available by email after successful registration.

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