美国药典在线点播课程 USP On-Demand Webinar

单克隆抗体治疗性药物的开发与表征

Development and Characterization of Monoclonal Antibody Therapeutics

课程时长 Course Duration: **59分钟** 59 minutes

课程介绍 Course Description:

许多单克隆抗体(mAbs)治疗性药物已获得许可或正在开发中，它们可用于治疗包括COVID-19在内的多种疾病。创新药和生物类似药的 mAb 蛋白需要多种测试方法来进行完全表征。这些测试方法的开发和验证具有挑战性，需要大量时间和资源来建立和维护。通过课程，您将了解到：

- 分析和支持 mAb 治疗性药物监管资料的最佳实践
- 生物类似药和创新单抗产品开发方法的差异
- 案例研究、共同挑战和缓解措施

通过学习，您将能够：

- 了解监管机构如何定义生物类似药、FDA 和 EMA 指南、以及 USP 相关通则
- 描述单克隆抗体治疗性药物的关键质量属性，以及用于评估其质量和确定生物类似性的分析技术
- 通过案例研究，解释如何确定生物制品的生物类似性

(本课程的现场版本录制于 2022 年 5 月 24 日)

Many therapeutic monoclonal antibodies (mAbs) have been licensed or are in development to treat a wide variety of diseases, including COVID-19. Innovator and biosimilar mAb proteins require multiple testing methods for complete characterization. These tests can be challenging to develop and validate, requiring significant time and resources to properly establish and maintain. Join USP and industry experts to learn about:

- Best practices to analyze and support regulatory dossiers for mAb therapeutic products
- Differences in approaches between biosimilar and innovator mAb development
- Using case studies, common challenges and mitigation approaches

Upon completion of this course, you will be able to:

- To understand how a biosimilar is defined by regulatory agencies and awareness of FDA and EMA guidance and supporting USP chapters.
- To describe critical quality attributes of monoclonal antibody therapeutics and the analytical techniques used to evaluate their quality and establish biosimilarity.
- To explain how biosimilarity may be established for biopharmaceuticals via evaluation of case studies.

(The live version of this recording took place on May 24, 2022)

参课对象 Who Should Attend:

本课程为执行、监督、管理、审核或监管单克隆抗体的开发、生产和质量评估的人员设计，包括：分析科学人员、研发人员、QC 人员、CRO/CMO 人员、生产科学人员和分析人员、法规监管人士等。

This course is designed for professionals who perform, supervise, manage, audit or oversee the development, manufacturing, and quality assessments of monoclonal antibodies including: Analytical scientists, R&D personnel, QC personnel, CRO personnel, CMO personnel, Manufacturing scientists and analysts, Regulatory personnel

授课语言 Language:

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

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单克隆抗体治疗性药物的开发与表征
Development and Characterization of Monoclonal Antibody Therapeutics

讲师介绍 Instructor:

Niomi Peckham, 美国药典委员会全球生物制品部门管线开发总监
Niomi Peckham, Director of Pipeline Development, 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 目前是美国药典委员会全球生物制品部门管线开发总监，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与建立。

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.

Gregory M. Beck, 前礼来公司研究顾问
Gregory M. Beck, Retired Research Advisor, Eli Lilly and Company

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

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.