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

生物制品的电荷变异分析

Analysis of Charge Variants in Biologics

课程时长 Course Duration: **1小时13分钟** 1hr and 13min

免费视频课！

课程介绍 Course Description:

课程将阐述电荷变异测定的重要性，介绍多种用于测定生物制品在开发、生产和稳定性测试期间变化的技术（例如离子交换色谱法、cIEF/icIEF），以及他们是关键质量属性的原因。其中包括方法开发的最佳实践，以及使用 USP 新单克隆抗体标准物质产生的数据。课程还将讨论各种正交方法的优缺点以及常见问题的解决方案。

通过学习本课程，您将能够：

- 阐述支持生物制品中关键质量属性测定的 USP 标准，尤其是针对单克隆抗体疗法；
- 描述用于测定生物制品电荷变异的方法；
- 解释如何解读这些方法得出的数据；
- 阐述如何利用这些方法产生的数据来支持生物制品的质量和保证稳定性。

（该课程的现场版本录制于 2020 年 12 月 9 日）

This course explains why measurement of charge variants is important. It will also describe multiple techniques (i.e., ion exchange chromatography, cIEF/icIEF) commonly used to measure changes in biologics during development, production and stability testing and why they are often CQAs. Best practices for development of methods are included as well as data generated with USP's new monoclonal antibody Reference Standards. The pros and cons of various orthogonal approaches along with troubleshooting common issues will be discussed.

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

- State the USP standards that support measurements of critical quality attributes in biologics and particularly monoclonal antibody therapeutics.
- Describe methods used to measure charge variants in biologics.
- Explain how to interpret the resulting data from these methods.
- Describe how the resulting data from these methods can be used to support the quality and stability assurance of biologics.

(The live version of this recording took place on December 9, 2020.)

参课对象 Who Should Attend:

药典联络官、咨询顾问、工程/制造人员、QA/QC 经理及员工、研发人员、法规人员、学生、CMO/CRO 人员等。

Compendial Liaison, Consultant, Engineering/Manufacturing Staff, QA Manager, QA Staff, QC Chemist, QC Manager, R&D Staff, Regulatory Staff, Student, CMOs, CROs

授课语言 Language:

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

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生物制品的电荷变异分析
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讲师介绍 Instructor:

Shyamosree Bhattacharya 博士，前美国药典委员会科学与标准副联络官
Shyamosree Bhattacharya, Ph.D., Former Associate Science and Standards Liaison, USP

Shyamosree Bhattacharya 博士是前美国药典委员会科学与标准副联络官。Bhattacharya 博士曾负责开发和维护各种生物制品的书面标准和标准物质，包括疫苗、mAbs、胰岛素和其他产品。在加入 USP 之前，她负责分析表征生物制品的 GMP 稳定性研究，拥有丰富的肽图研究和电荷变异分析方面的专业知识。Bhattacharya 博士在加尔各答大学完成了她的遗传学硕士学位，并在威斯康星大学麦迪逊分校获得化学生物学博士学位。

Shyamosree Bhattacharya was an Associate Science and Standards Liaison—Global Biologics for USP. As a liaison, Dr. Bhattacharya was responsible for development and maintenance of documentary and reference standards for a varied biologics portfolio that includes vaccines, mAbs, insulins and other complex products. Prior to USP, Dr. Bhattacharya oversaw GMP stability studies for analytical characterization biologics, with expertise in peptide mapping studies and charge variant analysis. Dr. Bhattacharya completed her Masters in Genetics from University of Calcutta, and her PhD in Chemical Biology from University of Wisconsin-Madison.

Niomi Peckham, 美国药典全球生物制品科学与标准联络官
Niomi Peckham, Science and Standards Liaison, 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 多家全球知名药企，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科学与标准联络官。她与业界专家和利益相关方合作共同负责 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。

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 a Science and Standards Liaison 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.

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.

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