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

质谱法测定生物药中残留宿主细胞蛋白的最佳实践：USP 通则<1132.1>

Best Practices for Residual Host Cell Protein Measurement in Biopharmaceuticals by Mass Spectrometry: USP Chapter <1132.1>

课程时长 Course Duration: **67分钟** 67mins

免费视频课！

课程介绍 Course Description:

以蛋白质为基础的生物治疗药物由许多原核和真核细胞表达系统生产。在这些产品的生产过程中，宿主细胞蛋白(HCP)是一类重要的工艺相关杂质，它会与预期产品一起产生。USP“通则<1132>生物药中残留宿主细胞蛋白测定”包含了关于测定这些残留 HCP 的试剂和免疫测定的设计、验证和实施的详细信息。新提议的通则（<1132.1>）建立在<1132>的基础上，概述了质谱(MS)方法用于 HCP 鉴别和定量的能力。本课程将介绍仪器选择、样品制备、液相色谱(LC)分离、质谱数据采集、质谱数据分析和报告的最佳实践，并特别关注质谱和传统方法的正交性。

Protein-based biotherapeutics are produced by numerous prokaryotic and eukaryotic cellular expression systems. During the manufacture of these products, host cell proteins (HCPs) are a significant class of process-related impurities that are coproduced with the desired product. USP General Chapter <1132> Residual Host Cell Protein Measurement in Biopharmaceuticals includes detailed information on the design, validation, and implementation of reagents and immunoassays used to measure these residual HCPs. A new proposed chapter builds on <1132> and provides an overview of the capability of Mass Spectrometry (MS) methods for HCP identification and quantitation. This seminar will describe best practices for instrument selection, sample preparation, liquid chromatography (LC) separation, MS data acquisition, MS data analysis and reporting, with particular attention to the orthogonality of MS and traditional methods.

参课对象 Who Should Attend:

负责生产和测试用于临床试验的生物制品的科学人员、管理人员和法规监管人员。

Scientists, managers and regulatory experts responsible for manufacture and testing of biologics destined for clinical trials.

授课语言 Language:

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

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Best Practices for Residual Host Cell Protein Measurement in Biopharmaceuticals by Mass Spectrometry: USP Chapter <1132.1>

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, 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。

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.

- **Ned Mozier, 辉瑞生物制药科学副总裁**
  Ned Mozier, Vice President, Biotherapeutics Pharmaceutical Sciences, Pfizer

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.

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