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

蛋白聚集与其他 100-20000 nm 颗粒（亚微米和不可见）的特性与生物相关性研究

Characterization and Biological Relevance of Protein Aggregates and Other Particles 100-20,000 nm in Size (Sub Micron and Subvisible)

课程时长 Course Duration: **60分钟** 60 minutes

免费视频课！

课程介绍 Course Description:

药品批次放行需要分析不可见和可见微粒，包括外源性微粒、生物制剂原料药中的蛋白质聚集物、微泡和硅油滴。近年来，相关分析技术以及了解和评估这些粒子的生物学后果的研究已取得了进展。在产品开发过程中，聚集物/微粒的特性应该成为产品特性的一部分，用于理解产品的正常特性。

课程将与您探讨大小从亚微米到可见微粒不等的微粒/聚集物的分析方法，着重讨论不可见微粒(1-100 μm)的分析方法。内容包括历史上安全问题的简要概述；整个行业的分析现状；讨论一个阶段性适合的、基于风险的方法。

Analysis of subvisible and visible particles—including foreign particles, protein aggregates from the API in biologics, microbubbles, and silicon oil droplets—is required as part of lot release. Recent years have seen advances in analysis technology, as well as studies to understand and assess biological consequences of these particles. Characterization of aggregates/particles should be part of product characterization during development, resulting in an understanding of what is normal for a product.

This webcast will explore the analytical methods available for particles/aggregates ranging in size from submicron to visible particles, with emphasis on the subvisible particles (1–100 µm).

Topics for discussion include:

- A brief overview of the historical safety concerns
- The current state of analysis across the industry
- A discussion of a phase-appropriate, risk-based approach

参课对象 Who Should Attend:

分析科学工作者、QA/QC 人员、R&D 研究员及其管理者、生产研究员及其管理者、法规事务专员、CMO 工作人员。

Analytical scientist, QA/QC analysts, R&D scientists and managers, Manufacturing scientists and managers, Regulatory affairs specialists, Contract manufacturing organizations.

授课语言 Language:

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

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讲师介绍 Instructor:

Linda Narhi 博士，美国药典委员会通则<788>注射剂微粒专家顾问组成员

Linda Narhi, Ph.D., Member of the USP Expert Panel <788> (Particulate Matter in Injections)

Linda Narhi 博士 2019 年从 Amgen 公司工艺开发科学组科学执行董事的职位上退休，作为顾问她将继续支持安进公司的治疗发展。她在美国密歇根大学获得化学学士学位，在加州大学洛杉矶分校获得生物化学博士学位。Narhi 博士于 30 多年前加入安进公司，一直致力于生物医药工艺和产品开发工作，包括蛋白质候选物的选择、蛋白质高阶结构的表征、蛋白质聚合物和微粒，以及研究蛋白质属性特别是聚合物对分子潜在免疫原性的影响。她在这些领域发表过大量文章。

Narhi 博士是 USP 生物制品不可见微粒分析专家顾问组成员、IQ 联盟生物制品 CMC 领导组成员、AAPS 蛋白聚集和生物学影响焦点小组前任主席。同时，她也是加州大学圣巴巴拉分校的兼职教授。她正在领导 AAPS 团队进行一项跨实验室研究，研究单克隆抗体聚集的产生和特性，以及它们对体外和体内模型系统的影响。

Linda Narhi recently retired as scientific executive director in the attributes science group in process development at Amgen, but continues to support therapudic development as a consuntant for this organization. She received her bacholoers in Chemistry degree from the University of Michigan and her doctorate in Biology Chemistry from UCLA. She join Amgen more than 30 years ago and has been involved in the procees and product development of Bio therepeudics throughout her carrer. this work includes protein candidate selection, charaterization of protein higher-order structure and protein aggregate and particles, and studying the impact of protein attributes, especially aggregates, on the potential immunogenicity of molecules. She's published extensively on these topics. Linda is a member of the USP Expert Panel on Subvisible Particle Analysis for Biologics, the Biologics of CMC Leadership Group of the IQ Consortium, and is former chair of the AAPS Focus Group on Protein Aggregation and Biological Consequences. She's also an adjunct professor at the university of California Santa Barbara. Linda is leading the AAPS community in undertaking a cross-lab study on the generation and characterization of monoclonal antibody aggregate and their effects on in vitro and in vivo model systems.

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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