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

USP 通则 <1049.1> 生物技术产品开发与生命周期管理的稳定性研究的设计

USP General Chapter <1049.1> Design of Stability Studies for Biotechnology Product Development and Lifecycle Management

课程时长 Course Duration: **70分钟** 70 minutes

免费视频课！

课程介绍 Course Description:

课程将向您介绍一个新的 USP 通则<1049.1>”生物技术产品开发与生命周期管理的稳定性研究的设计“。该通则提供了生物技术产品稳定性的指导和考量，着重于简化开发程序和实现可持续的商业产品效期。生物制品的稳定性往往对产品开发和市场注册造成速度上的限制。生物技术或生物医药产品本身很复杂，往往需要专门的技术和流程来确保其质量、安全和功效。任何药物产品的基本要求之一就是在整个产品保质期内保持产品的稳定性，从产品离开生产厂家的那一刻起直到被用于病人，必须确保产品的稳定性。

通过学习，您将能够了解与生物技术产品稳定性项目相关的法规要求和期望、了解如何设计从临床前到商业生命周期管理的稳定性策略、并解释生物技术产品稳定性测试的实例设计。

This webinar introduces a new USP General Chapter that provides guidance and considerations specific to biotechnology product stability with a focus to streamline development programs and achieve sustainable commercial product expiries. Stability of biologics often proves rate-limiting towards product development and market registration. Biotechnology or biological medicinal products are inherently complex, often requiring specialized technologies and procedures to ensure their quality, safety and efficacy. One of the essential requirements for any medicinal product is that product stability is maintained throughout the product shelf life. In addition, the stability of the product must be assured from the moment it leaves the company until it is administered to the patient.
Upon completion of this webinar, you will be able to understand the regulatory requirements and expectations related to biotechnology product stability programs, recognize how to design stability strategies from pre-clinical to commercial lifecycle management, and explain example designs for biotechnology product stability testing.

参课对象 Who Should Attend:

实验室经理、资深科学家、生物制药企业的研发/分析/QA/QC 人员；CDMO 和合同分析实验室技术人员；生物制品领域的监管专家。

- Lab managers, principal scientists, R&D, analytical, QA/QC scientists at biopharmaceutical companies
- Scientists at CDMO’s and contract analytical labs
- Regulatory experts working in the field of biologics.

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:

Camilla Santos 博士，美国药典委员会生物稳定性专家顾问组副主席；美国安进产品质量总监

Camilla Santos, Ph.D., Vice Chair of the USP Biologics Stability Expert Panel; Director Product Quality, Amgen

Camilla Santos 博士是美国 Amgen 公司产品质量总监，负责小分子和生物制品的临床与商业产品稳定性项目的策略、监督和管理工作，为从临床前毒理学阶段到商业生命周期项目管理的产品开发提供稳定性策略指导。

Dr. Camilla Santos is the Vice Chair of the USP Biologics Stability Expert Panel. As director of product quality at Amgen, Inc., she is responsible for the strategy, oversight, and management of Amgen's clinical and commercial product stability programs for small molecules and biologics, providing guidance on stability strategies to support product development from the preclinical toxicology stage through commerical lifecycle program management.

Lori McCaig 博士，USP生物稳定性专家顾问组成员

Lori McCaig, Ph.D., Member of the USP Biologics Stability Expert Panel

Lori McCaig 博士是 USP 生物稳定性专家顾问组成员。她在质量和稳定性项目管理方面有超过 20 年的工作经验。在成为独立咨询顾问之前，她在 Geneteech F. Hoffman-La Roche 公司从事全球质量控制工作，专注于产品注册和生命周期管理的全球战略、监督和管理研发和稳定性项目。

Dr. Lori McCaig is a member of the USP Biologic Stability Expert Panel. She has more than 20 years experience in quality and stability program management, most recently within the global quality control at Geneteech F. Hoffman-La Roche, LTD, with a focus on global strategy, oversight, and management of R&D and commercial stability programs for product registration and lifecycle management.

报名方式 Register Procedures:

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（报名成功后您会收到课程登录信息通知邮件）

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