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

ATCC-USP 研讨会：残留 DNA 测定
ATCC-USP Joint Webinar: Residual DNA Testing

免费视频课！

课程时长 Course Duration: 57分钟 57 minutes

课程介绍与目的 Course Description and Objectives:

本视频来自于 USP 和 ATCC 联合举办的“残留 DNA 测定”网络研讨会，重点关注生物制品中的残留 DNA 检测。课程将介绍 USP 通则<509>残留 DNA 测定，概述检测生物制品中大肠杆菌和中国仓鼠卵巢(CHO)基因组 DNA 的有效提取和 qPCR 方法。强调与这些基质相适应的 USP 标准物质的使用，并提供了这些标准物质的应用实例，用于测定样品中残留基因组 DNA 含量，以及分析方法系统适用性的重要论证。

此外，课程还将展示 ATCC 和 USP 联合推出的先锋性产品，这些产品专门用于提高生物制剂和疫苗开发过程中的质量标准并最大限度地降低风险。这些产品有助于使用疫苗和生物制剂生产中常用的经鉴定的细胞系的分析参考物质来评估残留 gDNA 的清除。通过学习，将获得以下方面的专业知识：残留 DNA 监控和控制、了解和实施通则<509>，以及有效利用 USP 标准物质和 ATCC-USP 联合推出的 gDNA 分析参考物质来确定样品中的残留 DNA 和评估分析方法性能。

USP and ATCC are collaborating to present the webinar “Residual DNA Testing” focused on Residual DNA detection in biologics for therapeutic use. This webinar will introduce USP General Chapter <509> Residual DNA Testing, outlining validated extraction and qPCR method for the measurement of E. coli and Chinese hamster ovary (CHO) genomic DNA within these biologics. Highlighting the use of USP Reference Standards catering to these substrates, the webinar provides the application examples of these RSs used for the determination of residual genomic DNA content in samples and for the crucial demonstration of system suitability for analytical procedures.

Additionally, the session will showcase the pioneering products jointly launched by ATCC and USP, specifically designed to elevate quality standards and minimize risks during the development of biological therapeutics and vaccines. These products facilitate the assessment of residual gDNA clearance using analytical reference materials derived from authenticated cell lines commonly employed in vaccine and biologic manufacturing. Attendees of this course will gain expertise in residual DNA monitoring and control, accessing and implementing General Chapter <509>, and effectively utilizing USP Reference Standards and ATCC-USP joint gDNA reference materials to determine the residual DNA in samples and assess analytical procedure performance.

参课对象 Who Should Attend:

QA/QC 专员与审核员；从事研发、制造和生产的实验室人员；制造领域的研究人员和管理者；CRO/CMO 企业人员；科研人员；批记录审核员；验证专员等。

Quality assurance and quality control specialists and auditors; Lab personnel in research and development, manufacturing, and production; Manufacturing scientists and managers; Contract research/manufacturing organizations; Scientists and researchers; Batch record reviewers; Validation specialists.

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:

Ying Han 博士，美国药典委员会全球生物制品部门资深科学家 II
Ying Han, Ph.D.，Senior Scientist II, Global Biologics, USP

Ying Han 博士是 USP 全球生物制品部门资深科学家 II。Han 博士致力于 USP 抗生素书面标准及相关标准物质。在加入 USP 之前，Han 博士曾任职于美国华盛顿特区多家生物技术/生物制药公司，负责生物制品的工艺开发、优化、验证和技术转让，包括重组蛋白、基因治疗产品和疫苗。Han 博士在同行评议期刊上发表了大量著作，并曾任《蛋白质表达与纯化》和《亚洲化学杂志》编委会成员。

Dr. Ying Han is a Senior Scientist II in USP's Global Biologics Department. Her work mainly focuses on the USP documentary standard development for a variety of biological products from antibiotics, peptides to complex biologics. She has a strong background and expertise on the development and regulation of drug products. Prior to joining USP in 2017, Dr. Han worked for several biotechnology/biopharmaceutical companies in the Washington, DC area, responsible for the process development, optimization, validation and technology transfer for biologics. Dr. Han is the author of numerous publications in peer-reviewed journals and served as an editorial board member for Protein Expression and Purification and Asian Journal of Chemistry.

Leka Papazisi, DVM, 博士，ATCC产品生命周期微生物研发部门首席科学家

Leka Papazisi, DVM, PhD, Principal Scientist, Microbiology R&D, Product Life Cycle, ATCC

报名方式 Register Procedures:

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