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

DNA 残留测定 Residual DNA Testing

课程时长 Course Duration: **40分钟 40 minutes**

课程介绍与目的 Course Description and Objectives:

DNA 残留测定被用于证明从生产细胞基质产生的宿主 DNA 在治疗用生物制剂中已完全被清除。课程概述了美国药典新提议的通则<509> DNA 残留测定，其中包含对大肠杆菌或仓鼠卵巢基因细胞 DNA 进行检测的药典方法。USP 提供了这些基质的基因组 DNA 的两个标准物质，用于确定样品中残留的基因组 DNA 含量，并确定分析方法的系统适用性。课程还将讨论 USP 通则<1130>核酸检测技术方法（DNA 残留测定）中分析其他残留 DNA 方法的最佳实践。

通过学习，您将能够：

- 确定测定残留 DNA 的通用程序（基于杂交、基于 DNA 结合蛋白和基于 PCR）；
- 考虑每种分析方法的优缺点，确定最适合您应用的分析方法；
- 描述基于 qPCR 的残留 DNA 方法；
- 了解并使用通则<509>；
- 阐明如何使用适当的标准物质来评估分析方法的系统性能。

Residual DNA testing is required for demonstrating clearance of DNA from the cell substrate used to manufacture biologics for therapeutic purposes. This webinar presents an overview of USP General Chapter <509> Residual DNA Testing, which contains validated measurement methods for E. coli and Chinese hamster ovary genomic DNA in such biologics. Two USP Reference Standards for the genomic DNA of these substrates have been developed to determine the residual genomic DNA content in a sample and to demonstrate system suitability for these analytical procedures. This course will also discuss best practices for other residual DNA methods that are found in USP General Chapter <1130> Nucleic-Acid Based Techniques—Approaches for Detecting Trace Nucleic Acids (Residual DNA Testing).

Upon completion of this course, you will be able to

- Identify common procedures (hybridization based, DNA-binding protein based, and PCR based) for testing residual DNA.
- Identify which assay format may be best for your application, taking into consideration the advantages and disadvantages of each assay.
- Describe the basis of a qPCR-based residual DNA method.
- Access and use General Chapter <509>.
- Illustrate how to use the appropriate Reference Standard to assess system performance for the analytical procedures.

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；制造业研究员和管理者；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.

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讲师介绍 Instructor:

Ying Han 博士，美国药典委员会全球生物部门科学与标准联络官
Science & Standards Liaison, Global Biologics, USP

Ying Han 博士是 USP 全球生物部门科学与标准联络官。她主要致力于 USP 文件标准以及通过抑菌活性分配效价的抗生素相关标准物质。在加入 USP 之前，Han 博士曾任职于华盛顿特区多家生物技术/生物制药公司，负责生物制剂的工艺开发、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 博士在同行评审期刊上发表了大量著作，并担任 Protein Expression and Purification 以及 Asian Journal of Chemistry 的编委。

Dr. Ying Han is a Science & Standards Liaison in USP's Global Biologics Department. She mainly works on the USP documentary standards and associated reference standards for antibiotics that still assign potency by antimicrobial activity. Before joining USP, Dr. Han worked for several biotechnology/biopharmaceutical companies in the Washington DC area, responsible for process development, optimization, validation and technology transfer for biologics, including recombinant proteins, gene therapy products and vaccines. 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*.

授课语言 Language:

中文 Chinese

课程有效期 Access Duration:

课程在线观看有效期：自在线报名并缴费成功日起，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.

培训费用 Fee: 200 元人民币/人 RMB200/attendee

报名方式 Register Procedures:

1. 请点击这里（课程报名）进行在线报名

   USP-China 收款账户： USP-China account
   收款人 Beneficiary： 美药典标准研发技术服务（上海）有限公司
   账号 Account No.： 6841 12464 120
   银行 Bank： 美国银行有限公司上海分行

2. 发票领取：快递/邮寄方式提供 Invoice is available after registration.

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