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

USP 抗生素标准和各论现代化策略

USP Antibiotic Compendial Standards and Modernization Approaches

课程时长 Course Duration: **86分钟** 86 minutes

课程介绍 Course Description:

越来越多的数据表明质量在抗生素抗药性中发挥着重要作用，所以确保抗生素的质量非常重要。美国药典拥有大量各论、通则和标准物质，支持通过发酵和化学合成方法生产抗生素。本课程主要关注复杂抗生素的分析方法，这些方法使用微生物检定法来确保原料药和产品的效力。课程涵盖以下主题：

- USP 书面标准和实物标准物质简介
- USP 抗生素标准的背景
- USP 通则<81>“抗生素-微生物检定法”中抗生素效价的圆柱平皿法和比浊法概述
- 新提议的 USP 通则<426>“组胺测试方法”
- 抗生素各论现代化的案例分析，包括：
  - 微生物检定转换，包括使用 USP 通则<1223.1>“抗生素微生物检定替代方法的验证”
  - 实施新的或改进的杂质方法以及挑战

通过学习，您将能够了解：

- 不同类型的 USP 标准
- 用于 USP 通则<81>“抗生素-微生物检定法”中测量抗生素效价的微生物检定方法
- USP 通则<426>“组胺测试方法”的目的和方法
- USP 通则<1223.1>的使用以及微生物生物测定和 HPLC 方法之间的桥接基础
- 推动 USP 各论现代化的合适方法

Ensuring the quality of antibiotics is more important than ever as additional data shows that quality plays a role in antimicrobial resistance. USP has a large portfolio of monographs, chapters, and reference standards that support antibiotics manufactured by both fermentation and chemical synthesis approaches. This webinar will primarily focus on analytical approaches for complex antibiotics that still use microbial assays to ensure potency of drug substances and products. The following topics will be discussed:

- Introduction to USP documentary and physical reference standards
- Background and context of USP antibiotics standards
- Overview of the cylinder - plate and turbidimetric methods for antibiotic potency in USP test General Chapter <81> Antibiotics—Microbial Assays
- Introduction to <426> Histamine Test Methods, a new proposed USP test general chapter
- Case studies that illustrate modernization of antibiotic monograph procedures including:
  - Microbial assay conversion, including use of General Chapter <1223.1> Validation of Alternative Methods to Antibiotic Microbial Assays
  - Approaches and challenges to implementing new or improved impurity methods

Upon completion of this course, you will be able to:

- Describe different types of USP standards
- Describe microbial assay methods used to measure antibiotic potency in USP test General Chapter <81> Antibiotics- Microbial Assays
- Describe the purpose and approach of proposed USP General Chapter <426> Histamine Test Methods
- Explain the use of General Chapter <1223.1> and the basis of bridging between a microbial bioassay and a HPLC method
- Detail suitable approaches to modernizing USP monographs

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参课对象 Who Should Attend:

微生物检定科学工作者，法规科学人员，分析员，QC/QA 人员，研发人员和管理者，CRO 企业人员等。
Microbial Assay Scientists, Regulatory Scientists, Analytical Scientists, QA & QC Staff, R&D Scientists and Managers, Contract Research Organizations.

讲师介绍 Instructor:

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

Ying Han 博士是 USP 全球生物制品部门科学与标准联络官。 她主要致力于 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 博士在同行评议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*.

Julie Zhang 博士，美国药典委员会全球生物制品部门科学与标准联络官- 部门主管
Julie Zhang, Ph.D., Science & Standards Liaison - Team Leader, Global Biologics, USP

Julie Zhang 博士是 USP 全球生物制品部门科学与标准联络官和部门主管。她的团队负责从抗生素、多肽到复杂生物制剂的各类产品的书面标准和标准物质的开发。Zhang 博士于 2017 年加入 USP，她的工作重点是遵循通则 <81> 抗生素-微生物检定法。Zhang 博士在药品的开发和监管方面拥有丰富的背景和经验。在加入 USP 之前，她曾任职于多家制药公司，在药品的开发和监管（例如方法开发和验证）方面拥有丰富的分析经验。

Dr. Julie Zhang is a Scientific & Standards Liaison and Team Leader in USP's Global Biologics Department. Her group is responsible for documentary standard and reference standard development for a variety of products from antibiotics, peptides to complex biologics. Dr. Zhang joined USP in 2017 and her focus was on the antibiotics that use microbial assay by following General Chapter <81>. Dr. Zhang has strong background and experience in the development and regulation of drug products. Prior to joining USP, she worked in pharmaceutical companies with strong analytical experience in the development and regulation of drug products such as method development and validation.

授课语言 Language:

英语（含中文字幕） English (with Chinese subtitles)

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课程有效期 Access Deadline:

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）

This course will be only available to you for 14 days from the day of successful registration or until you mark it 'Complete' in your transcript– whichever occurs first.

培训费用 Fee: 300 元人民币/人　RMB 300/attendee

报名方式 Register Procedures:

1. 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

2. 发票领取：电子发票通过电子邮件发送　e-Invoice is available by email after successful registration.

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