美国药典在线点播课程 USP On-Demand Webinar

微生物学和无菌保证
Microbiology and Sterility Assurance

课程时长 Course Duration: 5小时 5 hours

课程介绍 Course Description:

课程在 USP 通则<51>抑菌效力测试、<61>非无菌产品的细菌计数测试、<62>非无菌产品的微生物测试、<71>无菌测试、<1111>非无菌产品的药物制剂和药用原料的接受标准、<1115>非无菌药物原料和药品的微生物控制、<1227>微生物回收率验证、无菌保证、灭菌和微生物最佳实验室实践的框架下，全面阐述美国药典对微生物学和无菌保证的要求。

通过学习，您将了解：

- 美国药典在微生物学和无菌保证中的作用
- 《美国药典-国家处方集》(*USP-NF*)中的微生物测试类型
- 基于生长的药典微生物学测试的基础知识，包括其变异性
- 非无菌药品的微生物质量的抑菌效力测试、检测和验收标准的细节，生物负载控制和有害微生物，无菌测试，灭菌和无菌保证
- 微生物学的最佳实验室实践
- 参与美国药典标准制定的流程

This one-day course will offer participants a comprehensive insight into USP requirements for microbiology and sterility assurance in the context of USP General Chapters <51>, <61>, <62>, <71>, <1111>, <1115>, <1227>, Sterility Assurance, Sterilization and Best Laboratory Practices in microbiology.

In this course you will learn about:

- The role of USP in microbiology and sterility assurance
- Types of microbiology tests in the USP–NF
- Basics of growth-based compendial microbiology tests, including their variability
- Details of antimicrobial effectiveness tests, tests, and acceptance criteria for microbial quality of non-sterile pharmaceutical products, bioburden control and objectionable organisms, Sterility tests, and Sterilization and Sterility Assurance
- Best lab practices in microbiology
- Participation in the USP standards-setting process

参课对象 Who Should Attend:

QA/QC人员、法规事务经理、科学人员、研究员、监管专业人士、及其他在药品微生物实验室工作的专业人士。
QA/QC staff, Regulatory affairs managers, Scientists, Investigators, Regulatory professionals, other professionals who work or interact in a pharmaceutical microbiology laboratory environment.

授课语言 Language:

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

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微生物学和无菌保证 Microbiology and Sterility Assurance

讲师介绍 Instructor:

Radhakrishna Tirumalai 博士，美国药典委员会科学部门首席科学联络员
Radhakrishna Tirumalai, Ph.D., Principal Scientific Liaison, Science Division, USP

作为美国药典委员会科学部门首席科学联络员，Tirumalai 博士负责 USP 微生物专家委员会的科学事务联络工作。他与工业界、学术界、监管机构和其他科学组织紧密联系，致力于药典通则的开发和修订工作。Tirumalai 博士代表 USP 出任 PDA 微生物和无菌保证专家工作组和委员会委会；AAMI 微生、灭菌、无菌保证和生物相容性专家工作组成员；以及 FDA《药品微生物手册》编委会成员。

Tirumalai 博士拥有多年在制药界从事工艺与产品研发、转移和制剂生产的经验。他拥有生物化学博士学位。博士后期间主要从事对 HIV 和 MuLV 反转录酶和噬菌体 lamda 整合酶的研究，发表了数篇论著和综述。作为 USP 专业培训课讲师，Tirumalai 博士曾受邀于多个国内外会议上发表专题演讲，并在全球多个地方执教美国药典微生物主题培训课程。

Dr. Tirumalai is currently a Principal Scientific Liaison-General Chapters in the Science Division. He is the Staff Liaison to the USP General Chapters-Microbiology Expert Committee. He works with industry, academia, regulatory agencies and other external Science based organizations as the USP Expert Committee liaison in the development and revision of General Chapters in these areas. Dr. Tirumalai represents USP on PDA expert task forces and conference organizing committees related to Microbiology and Sterility Assurance, on AAMI expert working groups related to Microbiology, Sterilization, Sterility Assurance and Biocompatibility and on the editorial board of FDA's Pharmaceutical Microbiology Manual.
Dr. Tirumalai's prior industry experience encompasses process and product research and development, transfer, and product manufacturing. He has a Ph.D. degree in Biochemistry. His postdoctoral work included studies on HIV and MuLV reverse transcriptases and bacteriophage lambda integrase. He has authored numerous publications and review articles. He is a frequent speaker at conferences and has taught Pharmacopeial Microbiology courses at numerous locations globally.

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: 1,200 元人民币/人 RMB 1,200/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
   银行 Bank： 美国银行有限公司上海分行

2. 发票领取：报名成功后快递/邮寄方式提供 Invoice is available by express after successful registration

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