

邀请函 Invitation

美国药典委员会中华区总部诚挚地邀请您参加以下药典培训课程
USP-China sincerely invites you to attend the following USP Education course.

美国药典网络直播课程 *USP Live Webinar*

非无菌原料药和制剂的微生物质量控制和检测精要 Essentials of Testing and Control of Microbial Quality of Nonsterile Drug Substances and Products

课程时间 Date:

2021年3月23、24日上午8:30 am -12:00 pm (北京时间)
March 23rd and 24th, 2021, 8:30 AM-12:00 PM

课程简介 Course Description:

微生物检测是药品质量控制的重要环节，药品受微生物污染可能导致产品的有效成分活性降低，影响其安全性和有效性。近年来，随着全球医药科技的快速发展，药品微生物限度标准和检测手段逐步提高，国内药品企业对微生物检测的国际法规要求以及最新技术和理念的关注度在不断增加。

课程在介绍制药行业微生物规则要求的同时，全面阐述美国药典关于非无菌产品的微生物检测相关通则、良好微生物实验室管理等要求。内容涵盖：<51>抗菌有效性测试、<60>非无菌产品微生物检测—洋葱伯克氏菌群测试、<61>非无菌产品的细菌计数测试、<62>非无菌产品的微生物检测：控制微生物测试、<1111>非无菌产品的微生物检测：药物制剂和药用原料的接受标准、<1227>微生物回收率验证。

课程将有助于企业了解法规市场对非无菌原料药和制剂的微生物检测最新规定，帮助准确理解药典要求并评估可能对企业产生的影响。通过学习，您能了解美国药典在微生物和无菌保证中的作用；总结基于生长的药典微生物测试的基础知识，包括其可变性；能解释抗菌有效性测试的细节、非无菌产品的微生物检查、非无菌药品微生物质量验收标准的建议。

This course provides a comprehensive understanding of practices in the testing and control of bioburden/contamination of non-sterile drug substances and products in the pharmaceutical industry. It also gives an overview of the USP general chapters that address microbiological testing and bioburden control of nonsterile substances and products. USP-NF General Chapters <51> Antimicrobial Effectiveness Testing, <60> Microbiological Examination of Nonsterile Products—Tests for Burkholderia Cepacia Complex, <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests, <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms, <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use, and <1227> Validation of Microbial Recovery from Pharmacopeial Articles will be covered.

By taking this course, you will be able to explain the role of USP in microbiology and sterility assurance; summarize the basics of growth-based compendial microbiology tests, including their variability; explain the details of antimicrobial effectiveness tests, microbial examination of nonsterile products, enumeration and tests for absence of specified organisms, objectionable organisms and recommendations on acceptance criteria for microbial quality of non-sterile pharmaceutical products.

参加对象 Who Should Attend:

QA/QC人员、法规事务经理、实验员、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.

报名请登录 USP 会议与培训中文平台，[点击这里](#)（[课程报名](#)）在线报名（报名截止日：2021年3月16日）

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2021年3月23、24日上午8:30 AM-12:00 PM

讲师 Instructor:

Radhakrishna Tirumalai 博士，美国药典委员会科学部门首要科学联络人

Radhakrishna Tirumalai, Ph.D., Principal Scientific Liaison, Science Division, USP

作为美国药典委员会科学部门首要科学联络人，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员；AAMI 微生物、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 lambda 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.

授课语言 Language:

英文（配中文口译） English with Chinese interpretation

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2021年3月23、24日上午8:30 AM-12:00 PM

日程 Agenda:

时间 Time		主题 Topic	
第一天 Day 1 Mar. 23	8:30-8:35	Opening Remark	开场介绍
	8:35-9:30	通则<51>抗菌有效性测试	<51> Antimicrobial Effectiveness Testing
	9:30-9:40	休息	Break
	9:40-10:40	<61> 非无菌产品的微生物检测： 细菌计数测试	<61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests
	10:40-10:50	休息	Break
	10:50-11:30	<62> 非无菌产品的微生物检测： 控制微生物测试	<62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms
	11:30-12:00	问答	Q&A
第二天 Day 2 Mar. 24	8:30-8:35	Opening Remark	开场介绍
	8:35-9:25	<60> 非无菌产品微生物检测— 洋葱伯克氏菌群检测	<60> Microbiological Examination of Nonsterile Products Tests for Burkholderia Cepacia Complex
	9:25-9:40	休息	Break
	9:40-10:30	<1111> 非无菌药物制剂和药用原料 的接受标准及微生物污染控制	<1111> Acceptance Criteria for Nonsterile Pharmaceutical Preparations and Substances for Pharmaceutical Use, and Control of Micro Contamination
	10:30-10:45	休息	Break
	10:45-11:30	<1227>微生物回收率验证	<1227> Validation of Microbial Recovery from Pharmacoepial Articles
	11:30-12:00	问答	Q&A

This agenda is subject to change. 此表仅供参考，具体日程以最后版本为准

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培训费用 Fee: 2,000 元人民币/人 RMB 2,000/attendee

注：1、费用包含培训费、纸质讲义费。

Including training and printed teaching materials only.

2、若同一公司/单位选派3名以上人员参加此次培训，自第三人起可享受20%折扣。

The 3rd and more people from the SAME COMPANY can get 20% discount.

3、政府药检系统或科研院校，享受20%折扣。

20% discount will be offered to applicants from Government Labs and Universities.

报名方式 Register Procedures:

1. 在线报名、缴费（截止日：2021年3月16日） Make online registration and payment by Mar.16, 2021.

请点击[这里](#)（[课程报名](#)）进行在线报名

USP-China 人民币收款账户： USP-China account (RMB)

收款人： 美药典标准研发技术服务（上海）有限公司

账号： 6841 12464 120

银行： 美国银行有限公司上海分行

Bank Account No.: 12464120

Account Name: UNITED STATES PHARMACOPEIA STANDARD R N D AND TECHNICAL SERVICES SHANGHAI CO LTD.

Name of Bank: Bank of America, Shanghai Branch

Address: 16/F, AZIA Center, 1233 Lujiazui Ring Road, Shanghai 200120, China

SWIFT Code: BOFACN3X

CNAPS: 532290010011

2. 发票领取：课后快递/邮寄提供方式提供

Invoice is available after the course.

网络直播课登录方式 How to Access:

报名成功后，直播课登录信息（课程链接、密码）邮件将于课前三天左右发送至学员邮箱。请根据日程准时参课，逾期直播课通道将自动关闭。

Access information (including link and password) will be sent to participant's email address 3 days before the webcast after successful registration. The live webcast will only be available for access in the course duration.