美国药典在线点播课程 USP On-Demand 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 Course Duration: 6 小时 6 hours

课程简介 Course Description:

微生物检测是药品质量控制的的重要环节，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。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：通则<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。

（本课程的现场版本录制于 2021 年 3 月）

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.

(The live version of this recording took place on March 2021.)

参加对象 Who Should Attend:

QA/QC人员、法规事务经理、实验员、研究员、法规监管人员、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:

英文（含中文口译） English with Chinese interpretation

美国药典委员会中华区总部 USP-China
中国（上海）浦东新区洲海路 999 号森兰国际大厦 B 栋 801-804 室
Tel: (86) 21-68619800, Fax: (86) 21-68619810
E-mail: uspcn@usp.org, Website: www.usp.org

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Essentials of Testing and Control of Microbial Quality of Nonsterile Drug Substances and Products

讲师 Instructor:

Radhakrishna Tirumalai 博士，前美国药典委员会科学部门首要科学联络官
Radhakrishna Tirumalai, Ph.D., Ex-Principal Scientific Liaison, Science Division, USP

Tirumalai 博士是前美国药典委员会科学部门首要科学联络人，在 USP 任职期间负责 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 博士曾代表 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 an Ex-Principal Scientific Liaison-General Chapters in the Science Division. He was 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 represented 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

美国药典委员会中华区总部 USP-China
中国（上海）浦东新区洲海路 999 号森兰国际大厦 B 栋 801-804 室
Tel: (86) 21-68619800, Fax: (86) 21-68619810
E-mail: uspcn@usp.org, Website: www.usp.org