邀请函 Invitation

美国药典委员会中华区总部诚挚地邀请您参加 USP 网络直播课程
USP-China sincerely invites you to attend the following USP Live Webinar Education course.

美国药典网络直播课程 USP Live Webinar

分析方法的验证、确认和转移
Validation, Verification and Transfer of Analytical Procedures

课程日期 Date:

2022 年 3 月 15 日　**March 15, 2022**

课程简介 Course Description:

作为美国药典委员会的高级强化课程之一，“分析方法的验证、确认和转移”是基于美国药典<1224>、<1225>、<1226>一组通则开发的课程，旨在对制药及相关企业数据采集过程的质量控制提供专业指导。

根据美国药典通则<1225>要求和 ICH 指导原则，课程详细阐述小分子物质分析方法验证的性能参数（鉴别、杂质、含量分析等）和通则<1226>法定方法确认的要求。同时，还将介绍通则<1224>方法转移的要求，包含分析方法转移的流程构架、方法转移的类别（包括转移免除的可能性和转移过程的要素）、影响分析方法转移的重要因素、以及可采取的不同策略等内容。通过学习，您将对美国药典分析方法验证、确认和转移标准要求的理解更加深入和可操作。

As an enhanced course, “Validation, Verification and Transfer of Analytical Procedures” covers a family of General Chapters devoted to providing guidance for the quality of data-acquisition process.

It reviews parameters for validating analytical procedures for small molecules based on the USP General Chapter <1225> and ICH guideline. General Chapter <1226> Verification of Compendial Procedures and General Chapter <1224> Method Transfer will be discussed. It summarizes the types of transfers that may occur, including the possibility of waiver, and outline the components of a transfer process. In addition, it will cover the new General Chapter <1224> Method Transfer developed to provide a framework for analytical method transfer, examine different strategies, and discuss key factors that would influence the transfer of analytical methods from one site to another.

参加对象 Who Should Attend:

与分析方法验证、确认和转移工作相关的 QA/QC 部门、研发部门、项目管理部门、生产部门的实验室经理、分析化学师、研究员和法规符合人员（建议参加者在制药或相关行业有至少 2 年的工作经验）。

This course will benefit lab manager, analytical chemists, investigator or compliance staffs in QA/QC, R&D, project management, manufacturing, technical liaison, who are involved in the validation, verification and transfer of analytical procedures. You must have at least 2 years’ experience in pharmaceutical industry to get the full benefit of this course.

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：2022年3月7日）

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分析方法的验证、确认和转移
Validation, Verification and Transfer of Analytical Procedures

2022年3月15日

讲师 Instructor:

凌霄 博士， 美国药典委员会中华区对外事务总监 Xiao Ling, Ph.D., Director, External Affairs, USP China

作为美国药典委员会中华区对外事务总监，凌霄博士与政府、法规及利益相关方紧密联系，致力于推进 USP 在中国的使命和战略实施。她有超过 17 年分析化学领域政府实验室科研和管理的经验。加入 USP 之前，凌博士曾任山东省食品药品检验研究院抗生素室和辅料室主任，并拥有 4 年成功的 GMP 检查员和 1 年 CDE 药品审查中心药物研究审查员经验。她在支持药典各论开发、修订和质量控制方面有丰富的方法开发/验证和稳定性研究的实践经验，熟悉 FDA、ICH 等法规指南和药典标准（USP、EP、ChP）要求。凌博士拥有山东大学药学院天然药物化学博士学位。

As the Director of External Affairs - China, Dr. Ling closely works with government, regulatory and stakeholder to build and execute external affairs plan to advance USP's mission and strategic plan in China. She has over seventeen years of experience in both broad analytical chemistry laboratory in the authority lab with deep understanding of solid scientific and pharmaceutical regulation. Before joining USP China, she worked as Director of Antibiotics and Excipients Department, Shandong Institute for Food and Drug Control, NMPA, and has 4-year successful experience as GMP inspector in GMP inspection and on-site verification, and 1-year professional reviewer of pharmaceutical research in Center for Drug Evaluation of NMPA. She has rich hands-on experience in method development/validation, stability in support of monograph development, revision and quality control. And she's also in deep knowledge of regulatory guidelines (FDA, ICH etc.) GMP, USP, EP and ChP. Dr. Ling has a Ph.D. degree in Medicinal Chemistry of Natural Products, School of Pharmaceutical Sciences, Shandong University.

日程 Agenda:

时间 Time	主题 Topic	
9:00-12:00	**美国药典书面标准— 结构**	**USP Documentary Standards – Structure**
	USP 通则<1225>法定方法验证 — 验证参数：专属性、精密度、准确性、线性和范围、检出限 / 定量限、耐受性	**USP <1225> Validation of Compendial Procedures - Validation Parameters**: Specificity, Precision, Accuracy, Linearity and Range, Detection/Quantification Limit, Robustness
12:00-13:00	*午休*	*Noon Break*
13:00-17:00	**验证参数（续）** — 专属性、精密度、准确性、线性和范围、检出限 / 定量限、耐受性	**Validation Parameters (continue)** - Specificity, Precision, Accuracy, Linearity and Range, Detection/Quantification Limit, Robustness
	通则<1226> 法定方法确认	**GC<1226> Verification of Compendial Procedures**
	通则<1224> 分析方法转移	**GC<1224> Transfer of Analytical Procedures**
17:00-17:30	**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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2022年3月15日

培训费用 Fee：1,500 元人民币/人 RMB 1,500/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：2022 年 3 月 7 日） Make online registration and payment by Mar. 7, 2022.
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 will be sent to attendees by express after the course.

直播课登录方式 How to Access:

直播课登录信息（课程链接、密码）将于课前一周左右以邮件形式发送至学员邮箱。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 attendee's email address about one week before the webinar. The live webinar will only be available for access in course duration.

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