

美国药典在线点播课程 *USP On-Demand Webinar*

美国药典通则<1210> 验证方法的统计工具

USP-NF General Chapter <1210> Statistical Tools for Procedure Validation

课程时长 **Course Duration:**

3小时27分钟 3 hour 27 mins

课程介绍 **Course Description and Objectives:**

课程介绍了 USP 通则<1210>“验证方法的统计工具”的关键内容，包含准确性和精密度、统计等效性、检测限、定量限、案例分析等。USP 通则<1210>提供了方法验证的统计概念，它是对 USP 通则<1225>“药典方法验证”的补充。课程也会对 USP 通则<1225>的定义和验证参数进行概述。

通过学习，您将能够：

- 确定 USP 通则<1225>中所述分析方法的性能特征的选择
- 定义方法的“适用目的”
- 确定方法验证的方法和统计工具
- 正确应用统计工具和方法来验证生物分析方法
- 识别并避免在统计验证过程中可能导致合规性问题的常见行为

This course introduces key components of *USP-NF General Chapter <1210> Statistical Tools for Procedure Validation*. This chapter provides statistical concepts used for procedure validation and complements *USP-NF General Chapter <1225> Validation of Compendial Procedures*. The course will include an overview of USP <1225>. Upon completion of this course, you will:

- Identify the performance characteristics of analytical procedures described in USP <1225>
- Define “fit for purpose” with respect to a procedure
- Identify methods and statistical tools used for procedure validation
- Correctly apply statistical tools and methods used to validate bioanalytical procedures
- Recognize and avoid common actions that can result in compliance issues during statistical validation

参课对象 **Who Should Attend:**

分析化学人员、QA/QC 人员、研发人员、项目管理人员、生产人员、CRO、法规专员、涉及分析方法验证和确认的技术联络员。建议参课学员至少拥有两年制药行业工作经验。

Analytical chemists, QA/QC staff, R&D staff, Project management staff, Manufacturing staff, CROs, Regulatory professionals, Technical liaisons who are involved in the validation and verification of analytical procedures

NOTE: You should have at least two years' experience in the pharmaceutical industry to get the full benefit of this course.

授课语言 **Language:**

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

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讲师 Instructor:

Steven Walfish, 前美国药典委员会科学部门通则高级首席科学家

Steven Walfish, Former Sr. Principal Scientist, Science-General Chapters, USP

Walfish 先生曾任美国药典委员会(USP) 科学部门通则高级首席科学家，负责统计学专家委员会。在加入 USP 之前，他曾任职于 BD、GE Healthcare、Human Genome Sciences 和 Chiron 等公司。此外，Walfish 先生曾任 Statistical Outsourcing Services 公司总裁，为 FDA 监管行业提供统计分析和培训。Walfish 先生在开发和应用统计方法解决复杂的商业问题方面拥有 30 多年的专业知识，包含统计方法应用于分析方法验证、验证和稳定性分析的经验。Walfish 先生拥有布法罗大学(University of Buffalo) 统计学学士学位、罗格斯大学(Rutgers University) 统计学硕士学位和波士顿大学(Boston University) EMBA 学位。

Mr. Steven Walfish was the former Principal Science & Standards Liaison at United States Pharmacopeia (USP) responsible for the Statistics Expert Committee. Mr. Walfish has held roles at Becton Dickinson, GE Healthcare, Human Genome Sciences and Chiron. Steven was President of Statistical Outsourcing Services, a consulting company that provides statistical analysis and training to the FDA regulated industries. Steven brings over 30 years of industrial expertise in the development and application of statistical methods for solving complex business issues. Steven has experience applying statistical methods to analytical method verification and validation and stability analysis. Steven holds a Bachelors of Arts in Statistics from the University of Buffalo, Masters of Science in Statistics from Rutgers University and an Executive MBA from Boston University.

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 only be 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: 1200 元人民币/人 RMB 1200/attendee

报名方式 Register Procedures:

1. 请点击[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: 电子发票通过电子邮件发送 e-Invoice is available by email after successful registration.