美 国 药 典 在 线 点 播 课 程 USP On-Demand Webinar

USP 通则<1010> 分析数据的解读和处理
USP <1010> Analytical Data - Interpretation and Treatment

课程时长 Course Duration: **7.5小时** 7.5 hours

课程介绍 Course Description:

统计学广泛应用于医药行业，是药物研发和质量控制中数据处理和分析的重要理论基础。美国药典“通则<1010>分析数据的解读和处理”旨在规范实验分析数据的处理和解读，帮助从业人员正确运用统计学理论和工具解读药物分析过程中获得的实验数据。

为帮助非统计学专业人员更好理解美国药典通则<1010>中涉及到的统计学理论及具体应用，课程将对统计描述手段、统计区间的计算及应用、统计检验方法的选择、假设检验、统计效力检验及异常值检验等内容进行集中讨论。通过学习，您将熟悉美国药典中涉及到的统计学术语，初步了解正确分析解读实验数据的步骤和方法。

（该课程的现场版本录制于 2022 年 10 月 13-14 日）

This course expands on the key elements of USP–NF General Chapter <1010> concerning acceptable statistical concepts and practices for the analysis and interpretation of analytical data. Special emphasis is places on making statistical inference using statistical interval approaches, use of the right statistical methods to establish comparability, sample size calculation for significance and equivalent tests, outlier detection, and application of variance component analysis to tease out variations from different sources. At the conclusion of this course, participants should be able to define statistical concepts commonly encountered in the literature and the USP, describe the measures of central tendency and creation of confidence intervals, explain the use of hypothesis testing, select the appropriate statistical tests, and interpret statistical outcomes.

(The live version of this recording took place on October 13-14, 2022.)

参课对象 Who Should Attend:

生物/化学科研人员；QA/QC 人员；研发技术员和经理；统计学工作者；分析方法/流程/产品的设计、分析、开发和验证工作人员；法规事务专员；现场检查和 CMC 审核人员；生产技术员和经理等医药行业人士。

Biologists, Chemists, Analytical scientists, Quality engineers, Statisticians, those who are involved in design, analysis, development and validation of analytical procedures, processes and products, QA/QC analysts, R&D scientists and managers, Regulatory affairs specialists, Site inspection and CMC review chemists, Manufacturing scientists and managers.

授课语言 Language:

中文 Chinese

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讲师介绍 Instructor:

李健博士，美国药典委员会中华区信息研究与分析总监，美国药典委员会药典培训专家

Jay Li, Ph.D., Director, Market Research & Analytics, USP China; USP Professional Education Faculty

作为信息研究与分析总监，李健博士带领中国和印度团队为美国药典委员会提供量化决策研究、数据挖掘和数据可视化支持。李健博士有超过15+年的学术和业界经验，精通SAS，JMP， Tableau等数据分析软件。李健博士毕业于中国北京大学和美国南加利福尼亚大学，拥有心理学、统计学和经济学学位。

As the Director of Market Research & Analytics, Dr. Li leads USP China and USP India teams to provide advanced analytics and data visualization support for strategy development within the organization. With over 15 years' experience in academy and industry, he is proficient in several data analysis softwares, such as SAS, JMP, and Tableau., etc. He graduated from Peking University and University of Southern California with degrees in psychology, statistics and economics.

课程有效期 Access Duration:

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:

1800 元人民币/人　RMB 1800/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：快递/邮寄方式提供　Invoice is available after registration.

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