美 国 药 典 在 线 自 主 学 习 课 程 USP Self-paced Course

分析方法的生命周期和AQbD方法的应用

Analytical Procedure Life Cycle and Application of the AQbD Approach

课程时长 Course Duration: 12小时 12 hours

课程类型 Course Format: 在线自主学习模式 Self-paced

课程介绍与目的 Course Description and Objectives:

课程根据美国药典(USP)通则<1220>的要求，对如何应用分析方法的生命周期进行详细介绍。内容包含分析方法的属性和参数，与方法设计相关的风险，以及用于鉴定方法和进行持续性能确认的策略。

课程由多种模式组合而成，包括在线自主学习模块、网络直播案例研究和问答环节的录制视频，介绍各种软件程序的补充视频，以及知识测试等。

通过学习，您将能够：

- 根据 USP 通则 <1220>，定义分析方法的生命周期
- 解释分析目标概况(Analytical Target Profile)的重要性及其对方法的影响
- 理解 AQbD 在分析方法生命周期框架中的应用和重要性
- 了解适用于分析方法生命周期所有阶段的质量风险管理流程的关键方面
- 描述识别关键的方法质量属性、关键的方法参数和风险评估
- 解释如何建立分析方法性能表征标准
- 学习如何定义方法可操作设计区域（MODR）和建立方法的分析控制策略
- 了解如何使用软件来设计实验,并确认分析方法适合其预期目的
- 进行方法鉴定和持续的方法确认

Based on USP General Chapter <1220>, this course provides an understanding of how to apply the Analytical Procedure Life Cycle approach. Participants will examine analytical procedure attributes and parameters, risks associated with procedure design, and strategies used to qualify procedures and to perform continuous performance verification.

Course activities include self-paced e-learning modules, recordings of live virtual sessions, case studies to reinforce knowledge, supplemental videos featuring various software programs, and assessment containing the knowledge check questions.

Upon completion of this course, you will be able to:

- Define the Analytical Procedure Life Cycle, as per USP <1220>.
- Explain the importance of the Analytical Target Profile and its impact on a procedure.
- Understand the application and importance of AQbD within the APLC framework.
- Learn key aspects of the quality risk management process as applied to all stages of the APLC.
- Describe identification of critical procedure quality attributes, critical procedure parameters, and risk assessment.
- Explain how to establish Analytical Procedure Performance Characteristics criteria.
- Learn how to define Method Operable Design Region (MODR) and establish analytical control strategies for the procedure.
- Understand how software can be used to design experiments and confirm that an analytical procedure is suitable for its intended purpose.
- Conduct procedure qualification and ongoing procedure verification.

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讲师介绍 Instructor:

Horacio Pappa 博士，美国药典委员会科学部门通则高级总监
Horacio Pappa, Ph.D., Senior Director, General Chapters, Science-General Chapters, USP

Pappa 博士于2003年加入USP，目前担任科学部门通则处高级总监。他领导的USP通则科学联络员团队，负责六个专家委员会的工作。Pappa 博士在布宜诺斯艾利斯大学获得药物化学博士学位。他撰写了许多出版物和同行评议文章，并经常就色谱法和验证相关的主题发表演讲。在加入USP之前，他曾在制药行业从事QA/QC工作。Pappa 博士在布宜诺斯艾利斯大学药学系担任质量控制助理教授，并在 1997-2001 年期间担任阿根廷药典的执行秘书。他是由美国质量协会认证的质量工程师。

Dr. Pappa has been with USP since 2003. He is currently the Senior Director of the General Chapters Department, Science division of the USP. He provides scientific leadership to a team of scientific liaisons responsible for the activities of six different expert committees that cover the majority of the USP General Chapters. Horacio earned his Ph.D. in Pharmaceutical Chemistry from the University of Buenos Aires. He has authored many publications and peer-reviewed articles and is a frequent speaker and instructor on topics related to Chromatography and Validation. Prior to joining USP, he worked in the pharmaceutical industry in QA/QC. Horacio held the position of Assistant Professor of Quality Control in the Faculty of Pharmacy at Buenos Aires University, and Executive Secretary of the Argentine Pharmacopeia in the period 1997-2001. He is a Quality Engineer certified by the American Society for Quality.

Amanda Guiraldelli 博士，前美国药典委员会科学事务经理
Amanda Guiraldelli, Ph.D., Former Scientific Affairs Manager, USP

Amanda Guiraldelli 博士自 2012 加入 USP，在药典科学通则组担任科学事务经理和首席科学家。她曾是 USP 测量和数据质量专家委员会的科学事务联络官，从事制定和修订 USP 标准工作。在此之前，Guiraldelli 博士作为高级科学家在 USP 标准物质实验室工作了 8 年，从事药典标准的表征工作。她是巴西 Campinas 大学化学研究所的客座教授，是分析方法生命周期和 AQbD 相关主题的讲师。Guiraldelli 博士是色谱、质谱和化学计量学方面的专家，在医药研发领域拥有超过 14 年的经验。在加入 USP 之前，她是制药行业的研发科学家，也是德国柏林大学和荷兰莱顿大学（蛋白质组学和代谢组学中心）的客座科学家，致力于通过 LC-HRMS 对蛋白质进行表征研究，并使用 UHPLC-HRMS 进行方法开发。她毕业于药学生物化学专业，拥有巴西圣保罗大学分析化学博士学位。

Amanda Guiraldelli had been with USP since 2012 and held the position of scientific affairs manager and principle scientist in the compendial science group-general chapters. She was the scientific liaison to the USP Measurement and Data Quality Expert Committee, where she worked to develop and revise USP standards. Previously, Amanda worked as senior scientist at the USP reference standard laboratory for 8 years with characterization of compendial standards. She is visiting professor at the University of Campinas (UNICAMP) Brazil at the Institute of Chemistry and is a frequent speaker and instructor on topics related to analytical procedure life cycle and Analytical Quality by Design (AQbD). Amanda is specialist in chromatography, mass spectrometry and chemometrics and has more than 14 years of experience in pharmaceutical R&D areas. Prior to joining USP, she was R&D scientist in a pharmaceutical industry and visiting scientist at TU Berlin in Germany and Leiden University in Netherlands (Center for Proteomics and Metabolomics) working on proteins characterization by LC-HRMS and method development using UHPLC-HRMS. Amanda is graduated in pharmacy biochemistry and holds a Ph.D. in analytical chemistry from the University of São Paulo (metabolomics by UHPLC-HRMS, GC-MS and 1H NMR and chemometrics).

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参课对象 Who Should Attend:

药典联络员、QC化学分析人员、QA经理和员工、QC经理、研发人员、监管机构人员
Compendial Liaison, QC chemist, QA manager & staff, QC manager, R&D, Regulators

课程语言 Language:

英语 English

课程有效期 Access Deadline:

本课程在 USP-US 培训平台进行学习。

课程在线观看有效期：自报名并缴费成功日起 6 个月内有效，或者直到您将课程标记为“完成”- 以先到的日期为准。逾期课程访问通道将自动关闭。

This course will be only available to you for 6 months from the day of successful registration or until you mark the course ‘Complete’ in your transcript– whichever occurs first.

培训费用 Fee:

2,500元人民币/人 RMB 2,500/attendee

报名流程 Register Procedures：

1. 点击这里（课程报名）进行在线报名、缴费。 Click here for online registration and payment.

   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. 联系USP-China工作人员，获取上课链接。 Contact USP-China staff for access link.
   021-68619800 ext.8892，karen.fei@usp.org
   021-68619800 ext.7811，dw@usp.org

3. 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.