

美国药典在线点播课程 *USP On-Demand Webinar*

美国药典分析方法生命周期和 AQbD:

ICH Q14/Q2(R2) 及药典方法

USP Analytical Procedure Lifecycle and AQbD: ICH Q14/Q2(R2) and Compendial Approaches

课程时长 **Course Duration:**

3小时54分钟 3 hour 54 mins

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

美国药典委员会于 2024 年 4 月 15 日在中国上海举行了“分析方法生命周期和 AQbD 研讨会”。本课程的现场录制视频来源于此次研讨会中 Amanda Guiraldelli 的演讲。课程重点关注制药领域分析方法验证的演变，强调基于 AQbD 原则的“分析方法生命周期”模式。探讨药典方法，包括 USP 通则<1220>中的整体三阶段分析方法生命周期框架和其他 USP 验证相关章节。课程涵盖分析目标概况（ATP）、方法设计（第 1 阶段）期间 QbD 原则的应用，以及方法性能验证和持续监控（第 2 和第 3 阶段）等概念，包括在第 3 阶段可使用的工具（如控制图）以确保方法的适用性。课程还讨论 ICH Q14 和 Q2(R2) 指南，强调知识和质量风险管理的关键作用。

The U.S. Pharmacopeia held the 'USP Workshop on Analytical Procedure Lifecycle and AQbD' on April 15th, 2024. The recordings are from Amanda Guiraldelli's speeches on this workshop. This course will focus on the evolution of analytical procedures validation in the pharmaceutical landscape, emphasizing the "procedure life cycle" approach based on AQbD principles. Discussions will explore compendial approaches, including the holistic 3-stage procedure lifecycle framework from USP General Chapter <1220> and other USP validation-related chapters. Talks will cover concepts like Analytical Target Profile (ATP), application of QbD principles during procedure design (stage 1) and strategies for procedure performance qualification and ongoing monitoring (stage 2 and 3), including tools (e.g., control charting) that can be used to ensure procedure fitness for use at stage 3. The workshop will also address the implications of ICH guidelines Q14 and Q2(R2), emphasizing the key role of knowledge and quality risk management. *(The live version of this recording took place on April 15, 2024)*

参课对象 **Who Should Attend:**

小分子药和生物制品领域的原料药/制剂质量、研发人员；药典联络、法规事务人员；合同研究机构的实验室经理、分析化学师；法规监管人士；分析方法研究的学术机构/科研单位人员；以及其他对主题感兴趣的人员。

Chemical medicine and Biologics API/formulation QC/QA/R&D managers and staff; compendial liaison, regulatory affairs; CRO lab manager and analytical chemists; regulators; academic research involving analytical procedures; others interested in the topics

授课语言 **Language:**

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

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讲师 Instructor:

Amanda Guiraldelli, 前美国药典委员会科学事务经理

Amanda Guiraldelli, Former Scientific Affairs Manager, USP

Amanda Guiraldelli 曾是美国药典委员会科学事务部经理和药典通则首席科学家。她于 2012 年加入美国药典 (USP)。作为 USP 前测量和数据质量专家委员会科学联络官, 她曾负责分析方法生命周期及分析方法验证相关 USP 标准的制修订。此前, Amanda 在 USP 标准物质实验室担任高级科学家 8 年, 负责药典标准物质的表征。她是巴西 Campinas 大学 (UNICAMP) 化学研究所客座教授, 经常就分析方法生命周期、分析方法质量源于设计 (AQbD) 和色谱相关主题发表演讲及授课。Amanda 是质谱、色谱、组学和化学计量学方面的专家, 在药物研发领域拥有超过 15 年相关经验。在加入 USP 之前, 她任职于巴西制药行业担任研发科学家, 同时也是德国柏林工业大学和荷兰 Leiden 大学 (蛋白质组学和代谢组学中心) 客座科学家, 致力于通过 LC-HRMS 进行蛋白质表征以及使用 UHPLC-HRMS 进行方法开发。Amanda 毕业于圣保罗大学药学院药物生物化学专业, 被授予分析化学博士学位 (UHPLC-HRMS、GC-MS, ¹H NMR 代谢组学及化学计量学研究)。

Amanda Guiraldelli was the former scientific affairs manager and principal scientist in the compendial science group-general chapters at United States Pharmacopeia (USP). She joined USP in 2012. She was the scientific liaison to the USP Measurement and Data Quality Expert Committee, where she worked to develop and revised 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 graduates 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).

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: 500 元人民币/人 RMB 500/attendee

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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.