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

USP 通则<467>"残留溶剂检查法"和通则<1467>"残留溶剂 - 药典方法的确认与替代方法的验证"

USP General Chapters <467> *Residual Solvents* and <1467> *Residual Solvents - Verification of Compendial Procedures and Validation of Alternative Procedures*

课程时长 Course Duration: 2小时21分钟 2 hours and 21mins

课程介绍 Course Description:

本课程关注药物产品中残留溶剂的控制措施，旨在保障患者安全。课程主要基于 USP 通则<467>和<1467>（最新修订内容已于 2025 年 8 月 1 日生效）以及 ICH Q3C 指南，内容涵盖了残留溶剂的分类、允许限度及控制策略，包括未列出的溶剂的处理方案。同时，对残留溶剂的法规要求、鉴别、控制措施与定量分析进行介绍，并详细阐释分析方法及其适用性与替代方案。课程包含色谱图实例及相关条件说明。

课程主题包括：

- USP 通则<467>的历史方法和标准要求
- 基于风险的策略概念，以符合通则<467>的药物要求中的残留溶剂量
- 举例说明控制第 2 类和第 3 类残留溶剂的选项 1 和 2，以及 USP<467>中方法 A、B 和 C
- USP 通则<1467> 中所述的验证和确认要求、使用替代方法时的验证和确认要求
- 色谱系统与分析方法
- 有关残留溶剂的 FDA 指南及 CFR 条款
- USP 通则<467>和<1467>的最新修订

This course focuses on the control of residual solvents in pharmaceutical products to ensure patient safety. It is primarily based on USP General Chapters <467> and <1467>, and the ICH Q3C guideline. The course covers the classification, allowed limits, and control strategies for residual solvents, including what to do if a solvent is not listed. It also discusses regulatory aspects, identification, control, and quantitation of residual solvents, and provides detailed explanations of analytical procedures and criteria for their suitability and alternatives. The course includes examples of chromatograms with associated conditions.

Key topics include the following:

- Historical approaches and standards in USP General Chapter <467>
- Risk-Based Classification of Residual Solvents
- Risk-based strategy concept for complying with residual solvents content in pharmaceutical requirements of USP <467>
- Examples of using Options 1 and 2 for Control of Class 2 and Class 3 Residual Solvents, and Procedures A, B, and C as described in USP <467>
- Validation and verification requirements in USP General Chapter <1467>
- Validation and performance criteria when using alternative procedures
- Chromatographic systems and analytical procedures
- FDA guidance and CFR sections related to residual solvents
- The most recent revisions to USP <467> and <1467> (have been official on August 1st, 2025)

参课对象 Who Should Attend:

QC/QA，合规性人员，实验室分析员，制药和相关行业管理者，法规专员等。

QC/QA, Compliance staff, Laboratory scientists, Managers in the pharmaceutical and allied industries, Regulatory professionals.

授课语言 Language: 英语（带中文字幕） English (with Chinese subtitles)

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讲师介绍 Instructor:

Edmond Biba 博士，美国药典委员会通则科学部门资深科学家

Edmond Biba, Ph.D., Senior Principal Scientist, Science-General Chapters, USP

Edmond Biba 博士是 USP 通则-化学分析专家委员会和 USP 通则-物理分析专家委员会的资深科学家。自 2001 年加入 USP 以来，Biba 博士一直担任研发实验室和标准物质评估部的科学家。在加入 USP 之前，Biba 博士是美国国家研究委员会-沃尔特里德陆军研究所实验治疗部药物化学系的博士后研究员，从事生物检定导向药物发现、基于作用的设计机制、以及新抗疟药物的合成研究。Biba 博士拥有美国大学化学-合成有机化学博士学位，阿尔巴尼亚地拉那地拉那大学化学工程/化学专业学士学位。Biba 博士是 Sigma Xi-The Scientific Research Honor Society、美国化学学会、美国药物科学家协会、ICH Q3C(R8)工作组成员，以及药物质量研究所(PQRI)药物质量技术委员会成员。

Dr. Edmond Biba is a Senior Principal Scientist working with USP General Chapters-Chemical Analysis Expert Committee and USP General Chapters-Physical Analysis Expert Committee. Since Joining USP in 2001, Dr. Biba served as a scientist in the Research and Development Laboratory and in the Reference Standards Evaluation Department.
Prior to joining USP, Dr. Biba was a National Research Council-Walter Reed Army Institute of Research Postdoctoral Fellow in the Medicinal Chemistry Department of Experimental Therapeutic Division conducting research on bioassay directed drug discovery and mechanism of action-based design and the synthesis of new antimalarial drug candidates. Dr. Biba received his Ph.D. in Chemistry-Synthetic Organic Chemistry from the American University, Washington DC, and a B.Sc. in Chemical Engineering /Chemistry from University of Tirana, Tirana, Albania.
Dr. Biba is member of Sigma Xi- The Scientific Research Honor Society, American Chemical Society, American Association of Pharmaceutical Scientists, ICH Q3C(R8) Working Group, and a member of Pharmaceutical Quality Technical Committee of the Pharmaceutical Quality Research Institute (PQRI).

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 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: 700 元人民币/人　RMB 700/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：电子发票通过电子邮件发送　e-Invoice is available by email after successful registration

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