

美国药典在线点播课程 *USP On-Demand Webinar*

USP 通则<467>残留溶剂检测

Residual Solvents in *USP-NF*

课程时长 **Course Duration:** 2小时 2 hours

课程介绍与目的 **Course Description and Objectives:**

2019年3月1日，美国药典“通则<467>残留溶剂”的重大修订及其配套的通则“<1467> 残留溶剂-药典方法的确认和替代方法的验证”正式生效。2020年12月1日，通则<467>额外修订的部分正式生效，以与 ICH Q3C(R6) 保持一致，将甲基异丁酮从第3类残留溶剂重新分类为第2类残留溶剂，并添加了三乙胺作为新的第3类残留溶剂。课程还将讨论其他相关主题，包括 USP 通则<1467>中概述的残留溶剂测试的验证和确认。

通过学习，您将能够：

- 了解 USP 通则<467>的历史方法和标准
- 应用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
- 举例说明选项 1 和 2，以及 USP<467>中方法 A、B 和 C
- 区分验证和确认，并了解何时使用替代方法
- 了解 USP 通则<1467> 中所述的验证和确认要求

Significant revisions to standards for residual solvents found in *USP-NF* General Chapter <467> Residual Solvents became official on March 1, 2019. At the same time the companion USP chapter <1467> Residual Solvents-Verification of Compendial Procedures and Validation of Alternative Procedures became official. Additional revisions were made to USP <467> and became official on December 1, 2020 to align with ICH Q3C(R6) which reclassified methylisobutylketone from a Class 3 to a Class 2 residual solvent and added triethylamine as a new Class 3 residual solvent. Other related topics will be discussed including validation and verification of residual solvent testing as outlined in USP <1467>.

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

- Understand the historical approaches and standards contained in USP General Chapter <467>.
- Apply a risk-based strategy concept for complying with residual solvents content in pharmaceutical requirements of USP <467>.
- Illustrate Options 1 and 2, as well as Procedures A, B, and C as described in USP <467>.
- Differentiate between validation and verification and understand when to use alternative procedures.
- Understand validation and verification requirements as described in USP General Chapter >1467>.

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)

报名请登录 USP 会议与培训中文平台，[点击这里](#)（[课程报名](#)）进行在线报名。

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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首席科学家

Edmond Biba, Ph.D., 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首席科学家。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 Principal Scientist to the 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：快递/邮寄方式提供 Invoice is available after registration.