

美国药典组合课程 *USP Blended Course*

USP 通则<1469>亚硝胺杂质 - "在线点播课程+直播答疑"培训活动

USP <1469> Nitrosamine Impurities On-demand and Q&A Sessions

课程介绍 **Course Description:**

亚硝胺具有较高致癌性，近年来一些含有亚硝胺杂质的产品因安全问题被召回，使其成为全球药品监管机构和业界共同关注的课题。为帮助大家更好地了解当前亚硝胺杂质法规指南和美国药典通则<1469>的具体要求，我们将于 2026 年 4-5 月开展“在线点播课程+直播答疑”组合形式的培训活动。

[“USP 通则<1469>亚硝胺杂质及其实验室操作教程”在线点播课程](#)将对当前亚硝胺杂质的法规指南和美国药典通则<1469>“亚硝胺杂质”进行介绍。课程将介绍亚硝胺的来源，包括由其他杂质的存在而形成的亚硝胺、以及如何消除或降低亚硝胺的含量。还将对评估与控制原料药和制剂中亚硝胺的工具、以及 USP 通则<1469>的分析方法（包括标准物质的使用、操作过程中的注意事项等）进行介绍。此外，课程将讨论基于 ICH Q9 指南的风险评估方法、控制策略的开发，以及基于 ICH M7 指南的亚硝胺限值的计算、测试方法性能特征。此外，实验室操作视频教程将对课程所述的实验室方法的分步操作提供指导，重点阐述对每个操作流程进行问题排除的关键注意事项、挑战和建议（因仪器而异）。

通过学习，您将能够：

- 描述 USP 通则<1469>“亚硝胺杂质”的背景、范围和方法，以及适用的法规指南；
- 解释亚硝胺形成的途径和来源，以及风险评估工具和高级工艺流程，以制定控制策略；
- 描述如何根据亚硝胺的测试方法性能特点选择合适的分析方法；
- 讨论在不同分析方法中 USP 标准物质的正确使用和处理；
- 确定影响方法灵敏度和选择性的因素；
- 总结 USP 通则<1469>中描述的四种测试方法的主要考虑因素、挑战和方法条件、以及样品和标准品的制备。

Nitrosamines should be strictly controlled in medicine due to high carcinogenicity. They are a critical topic for regulators and industry given the recent safety recalls of several products containing this impurity. To help everyone better understand the current regulatory guidelines on nitrosamine impurities and the specific requirements of the USP <1469>, we will offer a training in the form of an "on-demand course + live Q&A session" from April to May 2026. This one-day course will provide attendees with an understanding of current regulatory guidelines and USP General Chapter <1469> Nitrosamine Impurities. The course will provide an overview of sources of nitrosamines including their formation from the presence of other impurities and how to eliminate or reduce levels of nitrosamines. Tools to assess and control nitrosamines in drug substances and drug products as well as in depth analytical procedures in USP <1469> including the use of the USP Reference Standard and precautions to be used during procedures will also be covered. The course will also address risk assessment methodology as per ICH Q9, control strategy development, calculation of nitrosamine limits as per ICH M7 as well as test method performance characteristics. Video tutorial product is designed to provide step-by-step tutorials of laboratory methods described in the USP General Chapter <1469> Nitrosamines Impurities course. Tutorials emphasize key considerations, challenges, and recommendations for troubleshooting each procedure (varies from instrument to instrument).

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

- Describe the background, scope and approach of USP <1469> Nitrosamine Impurities and applicable regulatory guidelines.
- Explain pathways and sources of nitrosamine formation along with risk assessment tools and a high-level process flow to develop control strategies.
- Describe how to select the appropriate analytical procedures based on test method performance characteristics for nitrosamine methods
- Discuss the proper use and handling of the USP reference standard in the respective analytical procedures.
- Identify factors which impact sensitivity and selectivity of methods.
- Summarize key considerations, challenges and method conditions along with sample and standard preparation of the four test methods described in USP <1469>

点播课程时长 On-demand Course Duration: 6小时35分钟 6 hours 35 minutes

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参课对象 Who Should Attend:

制药企业研发分析人员，制剂和原料药QC经理/技术人员，授权药品放行的QA人员，法规事务人员，辅料生产商等。

Analytical R&D scientists, QC managers, QC scientists (DS, DP), QA staff who authorize drug product release, Regulators affairs staff, Excipient manufacturers, etc.

授课语言 Language:

点播课程 - 英语（中文字幕） English (with Chinese subtitles)

直播答疑 - 英语（中文口译） English (with Chinese Oral Translation)

讲师 Instructor:

点播课程 On-demand Course:

Edmond Biba 博士，USP科学部门通则资深科学家

Mrunal A. Jaywant 博士，USP-印度 科学部门研发高级总监

Marcus Obeng 博士，USP标准物质实验室资深科学家II

Amanda Guiraldelli 博士，前USP科学事务经理

Mark Han，USP标准物质实验室资深科学家II

Qiyao Li, USP分析开发实验室科学家 IV

Eswara Raju Kosuri, USP药典开发实验室资深科学家 II

Allan T. Leeks, USP分析开发实验室科学家 IV

Anindita Sarkar, USP药典开发实验室高级经理

直播答疑 Live Q&A:

Naiffer Romero, USP科学事务资深科学家

课程说明 Access Deadline:

- 2026年4月15日-5月15日，报名并完成“USP通则<1469>亚硝胺杂质及其实验室操作教程”在线点播课程。点播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点播课程登录信息通知邮件**）

From April 15 to May 15, 2026, register and complete the on-demand online course. The on-demand 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.

- 2026年5月20日上午9:00-10:00，参加USP直播问答环节，与USP专家就日常工作中遇到的亚硝胺杂质相关问题进行实时互动和交流。直播答疑的会议链接将于会前2-3个工作日向学员发送。

Participate in the USP live Q&A session from 9:00 to 10:00 a.m. on May 20. Meeting link for live Q&A session would be sent via email 2-3 working days before the live meeting.

培训费用 Fee: 1500 元人民币/人 RMB 1500/attendee

报名方式 Register Procedures:

- 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

- 发票领取：课程结束后电子发票通过电子邮件发送

E-Invoice is available by email after successful registration.