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

## USP 通则<1469>亚硝胺杂质

## USP <1469> Nitrosamine Impurities

**课程时长 Course Duration:** 5小时45分钟 5 hours 45 minutes

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

亚硝胺因具有较高致癌性，在药物中应予以严格控制。近年来几种含有亚硝胺杂质的产品因安全问题被召回，对于监管机构和行业来说亚硝胺是一个重要话题。为期一天的课程将介绍当前亚硝胺杂质的法规指南和美国药典通则<1469>亚硝胺杂质的标准。课程将详细介绍亚硝胺的来源，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 ICH9 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。

*（该课程的现场版本录制于 2021 年 6 月 15-16 日）*

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. 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 ICH9, control strategy development, calculation of nitrosamine limits as per ICH M7 as well as test method performance characteristics.

The live version of this recording took place on June 15-16, 2021

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>

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### 参课对象 Who Should Attend:

研发生厂商，QC经理，QC人员(DS，DP)，辅料生产商，科研人员，负责药品放行的QA人员等。

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

### 授课语言 Language:

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

### 讲师介绍 Instructor:

Edmond Biba 博士，USP科学部门通则首席科学家
Edmond Biba, Ph.D., Principal Scientist, Science-General Chapters, USP

Mrunal A. Jaywant 博士，USP-印度 科学部门研发高级总监
Mrunal A. Jaywant, Ph.D., Senior Director R&D, India-Science, USP

Marcus Obeng 博士，USP标准物质实验室资深科学家II
Marcus Obeng, Ph.D., Senior Scientist II, Reference Standards Lab, USP

Amanda Mesquita Guiraldelli 博士，USP-巴西 科学事务经理
Amanda Mesquita Guiraldelli, Ph.D., Scientific Affairs Manager, Brazil, USP

Mark Han，USP标准物质实验室资深科学家II
Mark Han, Senior Scientist II, Reference Standards Lab, USP

### 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**：1,200 元人民币/人 RMB 1,200/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.

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