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

使用者决定的报告阈值

User-Determined Reporting Thresholds

课程时长 Course Duration:

1小时45分钟　**1 hour 45 mins**

课程介绍 Course Description and Objectives:

美国药典通则<477>“使用者决定的报告阈值”(*User-Determined Reporting Thresholds*)已于 2024 年 5 月 1 日正式生效。该通则为用户提供了一种基于风险的灵活方法来确定有机杂质的报告阈值，与产品各论测试方法的实施保持一致。课程将介绍 USP 通则<477>的详细内容，包含符合 ICH Q3A/Q3B 指南期望、产品考量、给药途径、最大日剂量。还将介绍从 US FDA 收到的关于 USP 固定报告阈值的意见及相关的利益相关者的事项，了解更为灵活的使用者决定的报告阈值、将其引入各论的时机、以及一些可能进行的修订，介绍如何让质量体系支持这种灵活参数。

（课程的现场版本录制于 2024 年 1 月 31 日）

USP General Chapter <477> which becomes official on May 1, 2024, provides users a risk-based, flexible approach for determining the reporting thresholds for organic impurities, aligned with their product-specific implementation of a monograph test procedure. Detailed information in USP General Chapter <477> will be discussed on the topics below:

- Alignment with International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q3A and Q3B guidelines expectations
- Product considerations
- Routes of administration
- Maximum daily dose

(The live version of this recording took place on January 31, 2024)

参课对象 Who Should Attend:

化学合成原料药和制剂各论的用户，分析化学人员，实验室经理，QA/QC 专员/经理/总监，生产经理，合规经理，药典事务专员，对原料药和制剂中的有机杂质感兴趣的制药领域专业人员/学者等。

Users of chemically synthesized DS and/or DP Monographs, Analytical Chemists, Laboratory managers, QA/QC staff/managers, Managers, Directors, Production Managers, Compliance managers, Compendial affairs personnel, All pharmaceutical professionals/academicians interested in organic impurities in DS and Drug Products

授课语言 Language:

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

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

使用者决定的报告阈值

User-Determined Reporting Thresholds

讲师 Instructor:

Nick Garito, 美国药典委员会科学部门小分子资深首席科学家
Nick Garito, Senior Principal Scientist, Small Molecules, USP

Nick Garit 是美国药典委员会科学部门小分子资深首席科学家。他与科学人员和专家志愿者合作，制定并维护小分子药物成分和药品的书面标准。在此之前，Nick 曾担任 USP 认证项目经理，主要负责指导生产商完成 USP 膳食补充剂产品的认证工作。加入 USP 之前，他曾任职于华盛顿两家制药公司，有近 20 年的行业经验。随后他成为独立顾问，专注于药品质量保证。他的行业经验包括药物分析（分析方法开发和验证）、QC 管理、QA 管理以及化学、CMC 变更的监管支持。他的工作重点是为小分子固体口服缓释剂提供从早期产品开发到商业化的分析和合规支持。

Mr. Nick Garito is a Senior Principal Scientist in USP's Small Molecules Department where he collaborates with scientific staff and expert volunteers to develop and maintain documentary standards for small molecule drug substances and drug products. Previously, Nick served as a manager with USP's Verification Programs where he was primarily responsible for guiding manufacturers through USP's dietary supplement product verification process. Before joining USP, Mr. Garito worked as an independent consultant focused on pharmaceutical quality assurance following a 19 year career serving in various positions with two pharmaceutical companies based in the Washington D.C. area. His industry experience includes pharmaceutical analysis (analytical method development and validation), QC management, QA management, and regulatory support for Chemistry, Manufacturing and Controls (CMC) changes. His primary focus while working in industry was in the analytical and regulatory compliance support of small molecule solid oral, controlled-release formulations from early stage product development through commercialization.

Antonio Hernandez-Cardoso, 美国药典委员会科学部门通则资深首席科学家
Antonio Hernandez-Cardoso, Senior Principal Scientist General Chapters, USP

自 2005 年 7 月起，Hernandez-Cardoso 博士一直在 USP 全球科学标准部门 (GSSD) 负责科学支持工作，尤其是科学通则部门。他支持物理分析专家顾问组、化学分析/剂型/测量与数据质量专家委员会，协调专家志愿者对通则进行开发和修订工作，并回答来自内部和外部的美国药典相关问题。他的专业领域包括原料药和制剂中杂质、制药用水和分析用水。Hernandez-Cardoso 博士是美国药学科学家协会（AAPS）的成员，也是国际制药工程协会的USP联络员。他在药典方面有14年的工作经验，曾为墨西哥药典开发对抗疗法、顺势疗法、草药药典、以及医疗器械和药房出版物工作。此外，他还在墨西哥国立自治大学教授药典主题和一般制药主题课程超过12年。

Since July 2005, Antonio has worked at USP providing general scientific support within the Global Science and Standards Division (GSSD), specifically in the General Chapters Department, coordinating the volunteer experts works for the development and revision of general chapters by supporting Expert Panels and Subcommittees of the Physical Analysis, Chemical Analysis, Dosage Forms, and Measurement and Data Quality Expert Committees, assisting in the development and revision of general chapters and responding to internal and external queries related to USP–NF. Specific areas of expertise include impurities in drug substances and drug products and water for pharmaceutical and analytical purposes. He is member of the AAPS and the USP liaison to the ISPE. Antonio brought fourteen years' experience in pharmacopeial issues working for the Mexican Pharmacopeia developing the Allopathic, Homeopathic, and Herbal Pharmacopeias, and special publications for medical devices and drugstores. Also, Antonio has taught compendial topics to the pharmaceutical industry and general pharmaceutical topics at the National Autonomous University of Mexico for over twelve years.

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

使用者决定的报告阈值

User-Determined Reporting Thresholds

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：350 元人民币/人　RMB 350/attendee

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.

美国药典委员会中华区总部 USP-China
中国（上海）浦东新区洲海路 999 号森兰国际大厦 B 栋 801-804 室（200137）
Tel: (86) 21-68619800, Fax: (86) 21-68619810
E-mail: uspcn@usp.org, Website: www.usp.org