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

元素杂质分析

Analysis of Elemental Impurities

课程时长 Course Duration: 5小时 **5 hours**

课程介绍 Course Description and Objectives:

作为业界和监管机构广泛关注的议题之一，美国药典通则“<232>元素杂质-限度”和“<233>元素杂质-方法”修订后通过凡例(General Notices)要求应用于所有 USP-NF 各论产品。课程详细介绍了现行 USP 通则<232>与<233>的范围和具体要求、及其实施方法与可接受标准。同时，美国 FDA 相关指南也将和基于风险的方法一起讨论。

通过学习，您将能解释美国药典通则<232>和<233>中要求的范围和变化；对基于风险的方法进行描述；解释如何设置合适的标准；描述准确性和精密度：限度检测 vs.定量杂质检测；确定合适的测试仪器（如 ICP-OES、ICP-MS、XRF 或 GFAA）；正确的样品制备；讨论、计划和实施一个成功的方法验证。

This course discusses revisions made to USP–NF General Chapters <232> and <233>. In addition to presenting and discussing the necessary changes, a brief description of methods and how limits apply to products will be addressed in the course. The guidance published by the Food and Drug Administration (FDA) in June 2016 and the implementation timeline that has led to the current standards will be discussed along with risk-based approach.
Upon completion of this course, you will be able to:

- Explain the scope and changes in the requirements of USP–NF General Chapters <232> and <233>
- Describe the risk-based approach
- Explain how to set appropriate specifications
- Describe accuracy and precision: limit tests vs. quantitative impurity tests
- Identify the appropriate instruments for testing (e.g., ICP-OES, ICP-MS, XRF or GFAA)
- Describe proper sample preparation
- Discuss, plan and implement a successful method validation

参课对象 Who Should Attend:

化学分析员，QA/QC 人员，法规符合经理，实验室经理，生产经理，监管机构人员，以及其他对 ICP-OES 和 ICP-MS 应用于 API、辅料和药品中金属分析感兴趣的医药行业人士。
Analytical chemists, QA/QC, compliance managers, lab managers, production managers, Regulatory professionals, and individuals in the pharmaceutical industry with an interest in the application of ICP-OES and ICP-MS to the analysis of metals in APIs, excipients, and drugs.

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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元素杂质分析
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讲师介绍 Instructor:

Nancy Lewen, 美国药典委员会化学分析专家委员会主席（2020）
Nancy Lewen, Chair of USP Chemical Analysis Expert Committee (2020)

Nancy Lewen 女士拥有超过 30 多年的制药行业经验。退休之后，她担任了 Analytical R&D 原子光谱实验室负责人一职。Nancy 女士作为 USP 专家志愿者已超过 10 年，她曾经担任元素杂质专家小组主席和通则<191>鉴别测试小组主席。她是 2020 届 USP 化学分析专家委员会主席。Nancy 女士在制药应用和原子光谱方面拥有多篇著作，并教授这些主题的课程。

Ms. Nancy Lewen has over thirty years of experience in the pharmaceutical industry and recently retired as the supervisor of the Atomic Spectroscopy Laboratory in Analytical R&D. Nancy has served as a USP volunteer for over 10 years, having chaired the Elemental Impurities Advisory Panel and the <191>—Identity Tests sub-committee. She was the chair of the Chemical Analysis Expert Committee (2020). Nancy has written papers and lectured on the subject of pharmaceutical applications of atomic spectroscopy and has taught several short courses on the subject.

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: 1200 元人民币/人　RMB 1200/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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