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

口腔吸入和鼻用药品
Inhalation and Nasal Products

课程时长 Course Duration: **2小时45分钟** 2 hours 45 minutes

课程介绍与目的 Course Description and Objectives:

课程详细介绍美国药典中与气雾剂和吸入药物的质量与性能相关的重要内容，包含通则<5>“吸入和鼻用药物的产品质量检测”、通则<601>“吸入和鼻用药物的产品性能测试”、及其他相关通则。

通过学习，您将能够：

- 通过口服吸入和鼻腔局部应用，确定与肺部有关的药物靶向
- 总结和讨论吸入式气雾剂/喷雾/粉末的理化性质和扩散机制
- 阐述与口腔/鼻腔吸入产品相关的质量检测和产品性能测试的重要性
- 明确 USP 通则<5>、<601>、<1601>、<1602>、<1603>、及<1604>草案的目的
- 了解用于确定吸入产品给药均匀性（DDU）和空气动力学粒径分布（APSD）的设备操作

（本课程的现场版本录制于 2022 年 4 月 20-21 日）

This course focuses on the major aspects related to the quality and performance of aerosols and inhaled medications as described in the *USP-NF* General Chapters *<5> Product Quality Tests for Inhalation and Nasal Drug Products*, General Chapter *<601> Product Performance Tests for Inhalation and Nasal Drug Products*, as well as other related chapters that will also be addressed.

Upon completion of this course, you will:

- Identify drug targeting as it relates to the lungs by oral inhalation and by topical application to the nasal cavity.
- Summarize and discuss the physical-chemical properties of inhaled aerosols/sprays/powders and mechanisms of dispersion.
- Explain the importance of quality testing and product performance as they relate to oral and nasal inhalation products.
- Identify the purposes of *USP-NF* General Chapters <5>, <601>, <1601>, <1602>, <1603>, and the draft version of <1604>.
- Understand the operation of the apparatuses for determining delivered drug uniformity (DDU) and aerodynamic particle size distribution (APSD) of inhaled products.

(The live version of this recording took place on April 20-21, 2022.)

授课语言 Language:

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

参课对象 Who Should Attend:

QA/QC经理和分析人员、分析科研人员及管理者、产品开发人员、法规监管人员、吸入药品法规监管科学顾问等。

QA/QC analysts and managers, analytical scientists and managers, product development staff, regulatory staff, consultants involved with regulatory science of inhalation products.

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口腔吸入和鼻用药品

Inhalation and Nasal Products

讲师介绍 Instructor:

Jolyon P. Mitchell 博士，美国药典委员会制剂通则专家委员会委员、气雾剂子委员会主席

Jolyon P. Mitchell Ph.D , General Chapters-Dosage Forms Expert Committee Member, USP

Mitchell博士是一名专项于对各类口服吸入药物进行实验室评估的专家顾问。他连续三届被任命为美国药典委员会制剂通则专家委员会委员（2010-2015/2015-2020/2020-2025），同时也是USP通则委员会气雾剂子委员会的主席。2013年9月之前，他一直担任Trudell Medical International公司的科学总监，负责各类气雾剂测试。Mitchell博士参与多个口腔吸入气雾剂行业组织，包括欧洲药用气雾剂小组(EPAG)，同时也担任国际药用气雾剂监管与科学联盟(IPAC-RS)的科学顾问。Mitchell博士也是英国皇家化学学会会士、特许科学家和化学家。他帮助创立了英国-爱尔兰气雾剂协会，是该协会的终身荣誉成员，也是美国医药科学家协会（口腔吸入和鼻用药品领域）和美国气雾剂研究协会（AAAR）的成员。Mitchell博士是西安大略大学和夏威夷大学希洛分校Daniel K. Inouye药学院的客座教授。自2009年以来，他是国际医学气雾剂学协会（ISAM）气雾剂学院的讲师。

Dr. Mitchell is a private consultant specializing in the laboratory evaluation of orally inhaled products (OIPs) of all types. He was appointed to the Expert Committee: General Chapters-Dosage Forms (GC-DF) of the USP for the 2010-2015, 2016–2020, and 2020-2025 terms, where he chairs the Aerosols subcommittee to the GC-DF Committee. He was Scientific Director of Trudell Medical International until September 2013, with responsibility for all aspects of in vitro aerosol testing. He is involved in several industry-wide organizations involved with inhaled medical aerosol delivery, particularly, the European Pharmaceutical Aerosol Group (EPAG), as well as serving as a Scientific Adviser to the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS). He is a Fellow of the Royal Society of Chemistry and a Chartered Scientist and Chemist. He helped found the UK-Irish Aerosol Society where he is an honorary life member. He is also a member of the American Association of Pharmaceutical Scientists (Inhalation and Nasal Community) and the American Association for Aerosol Research (AAAR). He is an Adjunct Professor at the University of Western Ontario and an Affiliate Professor at the Daniel K. Inouye College of Pharmacy of the University of Hawaii at Hilo. He has been a faculty member for the annual International Society for Aerosols in Medicine (ISAM) Aerosol School since 2009.

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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