

## 邀请函 Invitation

美国药典委员会中华区总部诚挚地邀请您参加以下药典培训课程  
USP-China sincerely invites you to attend the following USP Education course.

### 美国药典网络直播课程 *USP Live Webcast*

#### 药物产品的稳定性研究方案 Stability Program of Pharmaceutical Products

**课程日期 Date:**

2021 年 3 月 15 日 March 15<sup>th</sup>, 2021

**课程简介 Course Description:**

稳定性研究在药物产品开发过程中起着至关重要的作用。可持续的稳定性方案对新药注册和支持药品市场营销都非常关键。

课程通过全面阐述 FDA 与 ICH 指南、行业惯例以及美国药典相关要求，在法规、执行操作、测试、调查等方面对小分子药物的稳定性方案进行深入介绍。课程将讨论广泛应用于稳定性方案设计的 cGMP、USP、FDA、ICH、WHO 相关法规要求，为建立药品有效期和储存信息提供支持。同时，课程将对监控整个药品货架期质量的稳定性指示方法的开发和验证要求、简化试验方法（矩阵法和括号法）、稳定性数据评估和 OOS 调查等内容进行介绍。通过丰富的实例分析，您将学习如何设计兼具成本效益与合规性的全球稳定性方案。

Stability program plays a pivotal role in pharmaceutical development, thus a sustainable stability program is critical not only to new product registration but also to support marketing program for pharmaceutical products. This course presents a comprehensive overview of stability program for small-molecule pharmaceutical products. It will cover regulations, operations, testing and investigations. For regulations, cGMP, USP, FDA, ICH and WHO stability requirements for pharmaceutical products applied in designing stability programs to establish expiration dating and label storage will be discussed. Technical and regulatory aspects to design a global stability program which is cost effective and in compliance will be discussed in depth as well as the needs for stability-indicating methods to monitor product quality throughout its shelf life. Reduced testing will also be reviewed through matrixing and bracketing options. Stability data evaluation and Investigation of Out-of-Specifications will also be addressed.

**参加对象 Who Should Attend:**

QC 分析员/经理/总监、QA 人员、法规事务员、审查员、分析技术员、稳定性研究协调员、CMC 提交审核员等。参加者包括所有必须深入了解相关 FDA 法规和 ICH 指导原则以建立、实施和管理稳定性方案或测试的人员。

Quality Control (QC) analyst, managers, directors, Quality Assurance (QA), Regulatory Affairs, Investigators, Analytical Scientists, Stability Study Coordinators, CMC submission and review scientists. Because of its comprehensive content, this course will prove most valuable to those involved in conducting and managing stability testing or program. This includes those whose job responsibilities require an in-depth knowledge of FDA regulations and ICH guidelines as applied to establishing stability programs and conducting stability testing.

**讲师 Instructor:**

USP 资深药典培训特聘专家 The USP Professional Education Faculty.

报名请登录 USP 会议与培训中文平台，[点击这里](#)（[课程报名](#)）在线报名（报名截止日：2021 年 3 月 8 日）

## 美国药典网络直播课程 *USP Live Webcast*

### 药物产品的稳定性研究方案 Stability Program of Pharmaceutical Products 2021 年 3 月 15 日

#### 授课语言 Language:

中文授课（双语书面讲义） Chinese (bilingual printed teaching material)

#### 课程纲要与日程安排 Course Outline & Agenda:

#### 9:30-12:00 了解 cGMPs 的稳定性测试要求 Understanding cGMPs of Stability Testing Requirements

- 药物稳定性的重要作用 Critical Role of Drug Stability
- 中国 GMP 和 21 CFR 211 对稳定性的影响 Impact of Chinese GMPs and 21CFR211 on Stability
- ICH 方法和 Q1A ICH process and Q1A
- 用于全球申请提交的稳定性研究方案 Stability protocol for global submission

#### 稳定性指示方法介绍 Stability Indicating Test Methods

- ICH Q2 A/B 对验证的要求 ICH Q2 A/B on Validation
- USP 通则<1225>方法验证 USP <1225> Validation
- USP 通则<1226>方法确认 Method verification based on USP<1226>
- 稳定性指示测试方法 Stability-indicating test methods

#### 12:00-13:30 午休 Noon Break

#### 13:30-16:00 关键的稳定性方法 Critical Stability Operations

- 稳定性方法的关键步骤 Critical steps of Stability Process
- 矩阵法和括号法的简化试验 Reduce testing with bracketing and matrixing
- 矩阵法和括号法的优缺点 Benefits and drawbacks of bracketing and matrixing
- 稳定性数据评估 Stability Data Evaluation

#### 稳定性结果的 OOS 调查 Conduct Out-of-Spec investigation for Stability Results

- FDA OOS 指南草案和 FDA 调查指南 FDA draft guidance on OOS and FDA Guides to inspection
- 分析员与上级在 OOS 调查中的角色 Analyst's and supervisor's roles in OOS investigation
- 稳定性数据 OOT Out-of-Trend for Stability Data
- 确定纠正措施/预防措施 Determine Corrective Actions/Preventive Actions

#### 16:00-16:30 问答 Q&A

*This agenda is subject to change. 此表仅供参考，具体日程以最后版本为准*

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### 药物产品的稳定性研究方案

### Stability Program of Pharmaceutical Products

2021年3月15日

#### 培训费用 **Fee: 1,800 元人民币/人 RMB 1,800/attendee**

注：1、费用包含培训费、纸质讲义费。

Including training and printed teaching materials only.

2、若同一公司/单位选派3名以上人员参加此次培训，自第三人起可享受20%折扣。

The 3rd and more people from the SAME COMPANY can get 20% discount.

3、政府药检系统或科研院校，享受20%折扣。

20% discount will be offered to applicants from Government Labs and Universities.

#### 报名方式 **Register Procedures:**

1. 在线报名、缴费（截止日：2021年3月8日） Make online registration and payment by Mar.8, 2021.

请点击[这里](#)（[课程报名](#)）进行在线报名

USP-China 人民币收款账户： USP-China account (RMB)

收款人： 美药典标准研发技术服务（上海）有限公司

账号： 6841 12464 120

银行： 美国银行有限公司上海分行

**Bank Account No.:** 12464120

**Account Name:** UNITED STATES PHARMACOPEIA STANDARD R N D AND TECHNICAL SERVICES SHANGHAI CO LTD.

**Name of Bank:** Bank of America, Shanghai Branch

**Address:** 16/F, AZIA Center, 1233 Lujiazui Ring Road, Shanghai 200120, China

**SWIFT Code:** BOFACN3X

**CNAPS:** 532290010011

2. 发票领取：课后快递/邮寄提供方式提供

Invoice is available after the course.

#### 直播课登录方式 **How to Access:**

报名成功后，直播课登录信息（课程链接、密码）邮件将于课前三天左右发送至学员邮箱。请根据日程准时参课，逾期直播课通道将自动关闭。

Access information (including link and password) will be sent to participant's email address 3 days before the webcast after successful registration. The live webcast will only be available for access in the course duration.