

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.

药品的稳定性研究方案 Stability Program of Pharmaceutical Products

时间/地点 Time/Location:

2025年10月24日 中国·上海
October 24, 2025 Shanghai, China

课程简介 Course Description:

稳定性研究在药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、方法、操作、调查等方面对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 相关法规要求，为建立药品有效期和储存信息提供支持。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。此外，课程还将介绍 2025 年 4 月新发布的《ICH Q1 原料药和制剂的稳定性试验指南》草案，该草案对当前 ICH 稳定性指南系列 Q1A-F 和 Q5C 进行修订并整合，增加使用过程中的稳定性研究、短期稳定性研究、中间产品/中间体加工和保持时间、标准品稳定性研究、产品生命周期和建模等内容。

课程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 pharmaceutical products. It will cover regulations, operations, testing and investigations. For regulations, cGMP, USP, FDA and ICH 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. Besides, ICH Q1 Guideline 'Stability Testing of Drug Substances and Drug Products' draft version will also be introduced.

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，以及需要深入了解相关FDA法规和ICH指南以建立、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.

药品的稳定性研究方案
Stability Program of Pharmaceutical Products
2025 年 10 月 24 日 上海

讲师 Instructor:

USP 药典培训认证讲师 The USP Qualified Education Faculty

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 Course Outline & Agenda:**9:00-12:00 cGMPs 的稳定性试验要求 cGMPs of Stability Testing Requirements**

- 药物稳定性的重要作用 Critical Role of Drug Stability
- 21 CFR 211 - 成品药物 cGMP 规范的稳定性影响
Impact of Part 211 - cGMP Practices for Finished Pharmaceuticals on stability
- ICH 要求与 Q1A(R2) ICH process and Q1A(R2)
- 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(R2) 对验证的要求 ICH Q2(R2) 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

12:00-13:00 午休 Noon Break**13:00-16:30 关键的稳定性操作方法 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

16:30-17:00 问答 Q&A

This agenda is subject to change. 具体日程以现场版本为准

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2025 年 10 月 24 日 上海

培训地点 Location:

美国药典委员会中华区总部 USP-China

地址：上海市浦东新区洲海路 999 号森兰国际大厦 B 栋 801-804 室
(地铁 6 号线，洲海路站 1 号出口，距离目的地 1.4 公里左右)

电话：021-68619800 * 8892

备注：主办方不统一安排住宿，请学员自行安排。

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、资料费、日程表中提及的餐饮费；其它费用自理。

Including training, teaching materials, and catering indicated in the agenda 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所，享受 20%折扣。

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

报名方式 Register Procedures:

1. 请点击这里 ([课程报名](#)) 进行在线报名

在线报名、缴费 (截止日: 2025 年 10 月 17 日) Make online registration and payment by Oct. 17, 2025.

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

2. 发票领取: 课后发送电子发票至学员邮箱

E-invoice will be sent by email after the course.