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

美国药典辅料相关 GMP 通则概述

Overview of USP-NF GMP General Chapters Relevant to Excipients

课程时长 Course Duration: **5小时35分钟 5 hours 35 minutes**

课程介绍 Course Description:

课程将探讨药用辅料的本质特性及其与药物活性成分和药物成品的区别。课程将涵盖药用辅料的基础介绍，并对《美国药典-国家处方集》(*USP-NF*)中与药用辅料相关的通则进行系统综述。课程还将解读药用辅料生产质量管理规范(GMP)章节的最新修订与进展，并通过实际案例示范如何应用 USP 辅料通则内容，同时结合行业最佳实践与指导原则进行说明。

通过学习，您将能够：

- 了解药用辅料的定义和范畴
- 识别与药用辅料相关的差异和多样性
- 说明使用药用辅料的目的
- 解释与辅料相关的 USP 通则的重要性
- 总结以下通则的重要内容：
  - USP 通则<1078> 药用辅料生产质量管理规范
  - USP 通则<1195> 药用辅料重大变更指南
  - USP 通则<1080> 药用辅料分析证书

This course will explore the nature of excipients and how they differ from active pharmaceutical ingredients and pharmaceutical finished products. An introduction to excipients and review of USP–NF General Chapters related to pharmaceutical excipients will be covered. An explanation of recent updates and developments to excipient GMP chapters will also be covered. Real-world scenarios will be used to apply USP General Chapters information along with some industry best practices and guidance.

Upon completion of this course, you will be able to:

- Demonstrate knowledge of what pharmaceutical excipients are and what they are not.
- Identify differences and diversities associated with pharmaceutical excipients.
- Describe reasons for using pharmaceutical excipients.
- Explain the significance of USP General Chapters relevant to excipients.
- Summarize important elements of:
  - USP–NF General Chapters <1078> Good Manufacturing Practices for Bulk Pharmaceutical Excipients
  - USP–NF General Chapter <1195> Significant Change Guide for Bulk Pharmaceutical Excipients
  - USP–NF General Chapter <1080> Bulk Pharmaceutical Excipients – Certificate of Analysis

参课对象 Who Should Attend:

分析科学人员、QA人员、质量部门人员、辅料生产商、配药员、医药科学人员、法规事务人员、化学和生产控制审核员等。

Analytical scientists, Excipient manufacturers, Compounding pharmacy staff, Quality assurance, Quality unit personnel, Pharmaceutical scientists, Regulatory professionals, Chemistry and manufacturing control Reviewers.

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Overview of USP-NF GMP General Chapters Relevant to Excipients

讲师介绍 Instructor:

Irwin Silverstein 博士, 美国药典委员会辅料通则专业委员会委员、美国药典认证项目审计员
Irwin Silverstein, Ph.D. USP General Chapters-Excipients Expert Committee; USP Verification Program Auditor

Silverstein博士是药用辅料质量与法规顾问。他曾任ISP公司QA总监。自1991年以来，他一直与IPEC合作为药用辅料制定GMP要求。Silverstein博士曾担任IPEA副总裁兼首席运营官，并于2010年获得了辅料GMP认证项目的美国国家标准协会（ANSI)认证。他还曾是一些制药公司的特聘专家顾问。Silverstein博士目前从事美国药典认证项目的审计工作。他也是NSF委员，参与编写辅料GMP的ANSI标准。

Dr. Silverstein is a consultant in Quality and regulatory compliance with an emphasis on pharmaceutical excipients. Formerly the ISP Corporate QA Director, he has worked since 1991 with IPEC to develop appropriate GMP requirements for excipients. He was VP and COO of International Pharmaceutical Excipients Auditing (IPEA) and achieved ANSI accreditation in 2010 for the Excipient GMP Certification program. He was also a subcontracted expert consultant to pharmaceutical companies involved in Consent Decree with the FDA.Dr. Silverstein currently conducts audits under the USP Verification program and is a member of the NSF committee that wrote the American National Standard (ANSI) for Excipient GMP.

授课语言 Language: 英语（含中文字幕） English (with Chinese subtitles)

课程有效期 Access Duration:

课程在线观看有效期：自在线报名成功日起，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）

Access to this course expires 14 days from the date of 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：电子发票通过电子邮件发送 e-Invoice is available by email after successful registration.

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