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

良好文件管理规范(GDP)和 USP 通则<1029>

Good Documentation Practices (GDP) and USP–NF General Chapter <1029>

课程时长 Course Duration: 80分钟 **80 minutes**

课程介绍与目的 Course Description and Objectives:

良好文件管理规范(GDP) 对规范的生产和实验室环境至关重要。相关人员必须严格遵守 GDP，以确保对完成的工作可进行审查。在一个完善的质量体系中，所有的文件都要符合 GDP 的要求。本课程将涵盖 USP 通则<1029>内容和 GDP 的概述，包括编写和修改文档，以及美国 FDA 21 CFR Part 11(电子记录和电子签名)要求的适用于产品开发所有阶段的各种文件的指南。

通过学习，您将掌握良好文件管理规范(GDP)的定义、目的和重要性；识别 GDP 的通用规则和原理、记录要求、实验室一般记录文件的要求；正确处理电子记录和电子签名（21 CFR Part 11）；学习 USP 通则<1029>及其在 GDP 中的重要性；了解欧盟(Vol.4)药品管理条例的知识；识别并描述 FDA 关于 GDP 违规的警告后果。

Good Documentation Practices (GDP) is essential in regulated manufacturing and laboratory environments. Personnel in these fields need to closely adhere to GDP in order to ensure an auditable account of work performed. GDP is required for all documentation included in a fully developed quality system. This live webinar will cover USP–NF General Chapter <1029> and an overview of GDP, including guidance for writing and correcting documentation as well as the various documentation required by U.S. FDA 21 CFR Part 11 (electronic records and electronic signatures) as applicable to all stages of product development.

By taking this course, you will be able to:

- Recall the definition, purpose, and importance of Good Documentation Practices
- Identify: general rules and principles of GDP, records requirements, general laboratory notebook documentation requirements
- Explain the proper handling of e-records and e-signatures (21 CFR Part 11)
- Describe USP Pharmacopeia General Chapter <1029> and its importance in GDP
- Demonstrate knowledge of the rules governing medicinal products in the EU (Vol. 4)
- Identify and describe outcomes of FDA warnings related to lack of GDP compliance

参课对象 Who Should Attend:

研发/QA/QC/生产部门的实验员、研究员、批次记录审核员、QA/QC 专员和审计员、验证专员、生产人员等。

R&D, QA/QC, Manufacturing, Production personnel, Scientists, Researchers, Batch record reviewers, QA/QC specialists and auditors, Validation specialists.

授课语言 Language:

英语（含英文字幕） English (with English 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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讲师介绍 Instructor:

Andrea Darden，美国药典委员会质量保证经理

Andrea Darden, Manager, Quality Assurance, USP

Andrea Darden 女士是一位资深的质量专业人员，在生物药制造、质量控制和质量保证领域拥有丰富的专业背景。在质量体系审计有关合规性、文档管理、编写标准操作规程以及进行质量和文档培训方面拥有广泛的经验。Darden 女士获得了美国胡德学院（Hood College）法规符合硕士学位，是质量和组织卓越认证经理，同时她也是经美国质量协会（ASQ）认证的质量审计员和高级会员。Darden 女士自 2001 年起加入美国药典委员会（USP），在美国以及全球开展针对 USP 认证项目和 USP 供应商评估项目的 GMP 审计工作

Mrs. Andrea Darden is a seasoned quality professional with a strong background in bio pharmaceutical manufacturing, quality control and quality assurance. She has extensive experience in conducting quality systems audits for regulatory compliance, managing documents, writing standard operating procedures and conducting quality and document training. She has a Masters Certificate in Regulatory Compliance from Hood College and is a certified Manager of Quality and Organizational Excellence, and a certified Quality Auditor from American Society for Quality (ASQ). She is also a Senior member of ASQ. Andrea has been with the United States Pharmacopeial Convention since 2001 and has performed GMP audits nationally and internationally for the USP Verification Program as well as the USP Supplier Evaluation Program.

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用户名、密码邮件）

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: 600 元人民币/人　RMB 600/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.

美国药典委员会中华区总部 USP-China
中国（上海）自由贸易试验区富特北路 520 号（200131）
Tel: (86) 21-68619800, Fax: (86) 21-68619810
E-mail: uspcn@usp.org, Website: www.usp.org