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

人用疫苗的 GMP 生产和表征

Introduction to GMP Manufacturing and Characterization of Vaccines for Human Use

课程时长 Course Duration: **4.5小时** 4.5 hours

课程介绍 Course Description:

本课程概括介绍了疫苗的生产和特性（包括疫苗的类型/组成/功能）及良好生产规范 (GMPs) 的基本概念。 并对美国药典 (USP) 通则、国际协调委员会 (ICH) 和世界卫生组织 (WHO) 法规指南以及 WHO 生物标准化专家委员会制定的疫苗标准进行介绍。学员将通过练习和案例分析来强化知识要点。

通过学习本课程，您将能够：

- 根据 WHO 的要求，识别并讨论药品的 GMP 原则和药品质量体系
- 通过实践练习讨论关键变化对产品质量的影响
- 根据 WHO 的要求描述生物制品 GMP 生产的生命周期方法和期望
- 介绍对疫苗类型及其组成部分的基本理解
- 总结和讨论疫苗生产过程
- 解释 GMP 的基本概念
- 定义 SISPQ 的组成
- 总结 ICH 和 WHO 的重要性
- 识别并解释 ICH 指南- Q5B、Q5D
- 解释 ICH Q7、Q8、Q9 和 Q10，因为它们与制药质量体系 (PQS) 相关
- 通过实践练习和案例研究，展示和应用质量风险管理和 PQS 知识

This course provides a general overview of manufacturing and characterization of vaccines including vaccine types, components, and functions. Fundamental concepts of good manufacturing practices (GMPs) will be introduced to participants. USP general chapters, International Council for Harmonization (ICH) and World Health Organization (WHO) regulatory guidelines, and vaccine standards developed by the WHO Expert Committee for Biological Standardization will also be addressed. Participants will engage in practical exercises and case studies to reinforce key learning points.

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

- Identify and discuss the main good manufacturing practice (GMP) principles for pharmaceutical products and the pharmaceutical quality system according to the WHO
- Discuss the impact of critical changes on product quality through practical exercises
- Describe the lifecycle approach and expectations for GMP production of biological products in terms of the WHO
- Demonstrate a basic understanding of the types of vaccines and their components through discussion and recall activities
- Summarize and discuss the vaccine manufacturing processes
- Explain the fundamental concepts of GMP
- Define the components of SISPQ
- Summarize the importance of the ICH and WHO
- Identify and explain ICH guidelines—Q5B, Q5D
- Explain ICH Q7, Q8, Q9, and Q10 as they relate to pharmaceutical quality systems (PQS)
- Demonstrate and apply knowledge of quality risk management and PQS through practical exercises and/or case studies

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参课对象 Who Should Attend:

研发细胞生物学家、研发制造商、研究分析员、生物技术生产商、药物微生物学家等

R&D Cell Biologists, R&D Manufacturers, Research Scientists, Biotechnology Manufacturers, Pharmaceutical Microbiologists

讲师介绍 Instructor:

Victor Maqueda, 美国药典委员会顾问 USP Consultant

Victor Maqueda 先生在制药领域拥有 30 年的资深工作经验，担任与 WHO、美国、欧盟标准相关的国际审计师和顾问。

他是世卫组织外聘审计员和顾问。自 2002 年起担任日内瓦世界卫生组织的外部审计员、顾问和培训师，对联合国疫苗供应商（印度尼西亚、中国、印度、韩国、欧洲、美国、加拿大、俄罗斯和巴西）和疟疾、艾滋病毒、肝炎（印度、日本）的体外诊断快速检测进行审计。完成 30 多次世卫组织资格预审的审计工作，是 WHO TRS 的官方审查员（例如，新版生物 GMP 要求，TRS 999）。

Victor Maqueda 先生也是 GMP 和质量体系培训师、审计员和顾问。自 2001 年以来，在制药、疫苗和医疗器械领域从事 cGMP 培训、审计和辅导工作，包括厂房设计、验证和确认、注射剂和眼科产品的无菌工艺操作、灭菌工艺（蒸汽、环氧乙烷、干热和伽马辐射灭菌）。对中国和意大利的经销商与原料药供应商进行第三方审计。为印度、美国和墨西哥药厂提供 GMP 咨询，并担任 ISO 9001/13485 主审员。

Thirty years of international, senior level experience in the pharmaceutical field in the private industry and as international auditor and consultant, as per WHO, US and EU standards.

- WHO external Auditor & Consultant. Since 2002 as external auditor, consultant and trainer for the World Health Organization, Geneva, to qualify UN suppliers of vaccines (Indonesia, China, India, South Korea, Europe, US, Canada, Russia and Brazil), and in-vitro diagnostics rapid tests for Malaria, HIV, Hepatitis (India, Japan). More than 30 audits for WHO Prequalification performed. Official WHO reviewer of WHO TRS (e.g., new GMP's for Biological, TRS 999).
- GMP & Quality System Trainer, Auditor & Consultant. Since 2001. Pharmaceutical, Vaccine & Medical Device industries. cGMP training, auditing, and coaching. Plant design. Validation & Qualification. Aseptic process operations for injectable and ophthalmic products. Sterilization processes (steam, ethylene oxide, dry heat and gamma radiation sterilization). Third party audits of Distributors and API suppliers in China, Italy. GMP Consultancy in pharmaceutical plants in India, US and Mexico. ISO 9001/13485 Lead Auditor.

授课语言 Language:

英语 (含英文字幕) English (with English subtitles)

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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: 700 元人民币/人　RMB 700/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 successful registration.

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